

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

NATURAL ALTERNATIVES INTERNATIONAL,) Civil Action
INC., et al.,)
)
Plaintiffs,)
)
v.)
)
VITAL PHARMACEUTICALS, INC., et al.,)
)
Defendants.) No. 09-626-GMS

- - -

VITAL PHARMACEUTICALS, INC.,)
)
Counterclaim/Third-)
Party Plaintiff,)
)
v.)
)
NATURAL ALTERNATIVES)
INTERNATIONAL, INC., and COMPOUND)
SOLUTIONS, INC.,)
)
Counterclaim/Third-Party)
Defendants.)

- - -

COMPOUND SOLUTIONS, INC.,)
)
Third-Party Plaintiff,)
)
v.)
)
DNP INTERNATIONAL CO., INC.,)
)
Defendant.)

- - -

Wilmington, Delaware
Thursday, May 12, 2011
9:30 p.m.
Markman Hearing

BEFORE: HONORABLE GREGORY M. SLEET, Chief Judge

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APPEARANCES:

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-and-
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Counsel for Defendant
DNP International, Inc.

1 THE COURT: Good morning, counsel. Counsel,
2 please take your seats.

3 Why don't know we start out with a round of
4 reintroductions, beginning with plaintiff.

5 MR. MOORE: Good morning, Your Honor. David
6 Moore from Potter Anderson on behalf of the plaintiffs.
7 With me today, closest to me Scott Chambers, John McKeague,
8 Richard Oparil, and Kevin Bell from Patton Boggs.

9 THE COURT: Good morning.

10 (Counsel respond "Good morning.")

11 THE COURT: Mr. DiGiovanni, good morning.

12 MR. DiGIOVANNI: Good morning, Your Honor.
13 Frank DiGiovanni from Connolly Bove. With me representing
14 one of the two defendants, Vital Pharmaceuticals, is my
15 partner Keith Walter.

16 THE COURT: Mr. Walter.

17 MR. WALTER: Good morning, Your Honor.

18 THE COURT: Counsel.

19 MS. KRAMAN: Good morning, Your Honor.

20 THE COURT: Good morning. I don't think we have
21 had the pleasure.

22 MS. KRAMAN: Pilar Kraman from Young Conaway. I
23 am here representing DNP International. With me is Steve
24 Hansen.

25 MR. HANSEN: Good morning, Your Honor.

1 THE COURT: Good morning.

2 Counsel, it seems like we have allotted four
3 hours for this.

4 MR. CHAMBERS: Yes, Your Honor.

5 THE COURT: If memory serves. I certainly hope
6 we don't take four hours. If it is looking like we are
7 going to need the full allotment, I am probably going to
8 want to break for lunch around 12:30. If you think we can
9 get finished by 1:00, that would be a good thing.
10 Otherwise, I am going to get hungry and irritable after
11 that. I am being a little facetious.

12 Have you discussed among yourselves how you
13 would like to proceed this morning?

14 MR. CHAMBERS: Yes, Your Honor, we have, at
15 least in the beginning. We have agreed to the fact that the
16 terms beta-alanine and L-histidine should be construed
17 together. And then plaintiffs believe that active
18 derivative should be construed at the same time. But
19 defendants believe that it should be construed separately.

20 THE COURT: When you say construed, you mean
21 argued.

22 MR. CHAMBERS: Argued, yes.

23 THE COURT: I guess I do the construing and you
24 do the arguing.

25 MR. CHAMBERS: I am sorry.

1 The reason is, a lot of the evidence that goes
2 to describing what an active derivative is also supports
3 plaintiffs' view of what beta-alanine is. So we think it
4 makes most sense to put them together.

5 We could either go term by term or we could go
6 all at once and you could pepper the argument with questions
7 as we go through, or however you would like to do it.

8 THE COURT: Well, on the term-by-term point, do
9 counsel have an agreement as to process on that?

10 MR. DiGIOVANNI: Your Honor, actually, we had
11 agreed that we would go term by term. I thought the only
12 disagreement was whether to include within the
13 beta-alanine/L-histidine argument the argument with regard
14 to active derivative.

15 MR. CHAMBERS: I hadn't heard that before.

16 THE COURT: Is term by term acceptable to
17 plaintiff?

18 MR. CHAMBERS: Term by term will be fine,
19 especially if we can keep the three together.

20 THE COURT: Let's talk about that for a minute.

21 MR. DiGIOVANNI: Your Honor, we did not brief
22 the three together. The L-histidine and beta-alanine were
23 briefed together. And we believe that active derivative
24 should be handled separately, although immediately after the
25 beta-alanine and L-histidine argument. I think there are

1 certainly some differences between what ought to be used to
2 construe those claims or that particular claim term.

3 THE COURT: When you say what ought to be used,
4 what are you talking about?

5 MR. DiGIOVANNI: I am talking about the
6 various -- well, active derivative is actually a term that
7 didn't come until one of the later patents. It doesn't even
8 appear in the first patent. So I think some of the
9 arguments that are going to be made don't pertain to active
10 derivative.

11 So we think the beta-alanine and L-histidine
12 should be handled separately, or else there is going to be
13 some issues that could get confused together. We think,
14 just like in our briefing, they ought to be handled
15 separately, although immediately thereafter.

16 MR. CHAMBERS: Your Honor, when you look at our
17 briefing, you find that some of our discussion of active
18 derivative, in fact, the way that we interpret active
19 derivative is within the context of the claims.

20 Now, active derivative goes to a Markush group,
21 and the Markush group and says a beta-alanine, an ester of
22 beta-alanine, or an amine of beta-alanine. So active
23 derivative has to go with those three terms. Otherwise,
24 it's just, you know, trying to determine what it means in a
25 vacuum.

1 THE COURT: You are essentially saying just what
2 he just said: The Court needs context, essentially, in
3 order to properly construe.

4 MR. CHAMBERS: Yes. We will be repeating some
5 of the same evidence if we do it --

6 THE COURT: What if any prejudice would either
7 defendant suffer were I to accept the approach, not talking
8 about the substantive arguments, just the approach that is
9 being suggested by plaintiff?

10 MR. DiGIOVANNI: Your Honor, I would say there
11 is no prejudice. I would just say from an organizational
12 standpoint, it's better to take the active derivative term
13 separately.

14 THE COURT: Do you think it will confuse things
15 for me?

16 MR. DiGIOVANNI: Not for you, Your Honor. I
17 just think, generally, most of the record does not overlap
18 in terms of active derivative, so it makes sense to keep it
19 together.

20 THE COURT: Here is what I will do. I am going
21 to accede to the urgings of plaintiffs' counsel. To the
22 extent that defendants want to call out differences or
23 reasons why I should be mindful of the fact that active
24 derivative was not included in the briefing in the manner
25 suggested or that it is going to be presented today and to

1 the extent that that will inform my efforts, I will
2 certainly wait on that.

3 So that is what we will do.

4 I notice one of the parties included some
5 guidance in its discussion of the applicable law on
6 extrinsic evidence, I am not sure which one, I don't
7 remember. I wanted to make sure its clear, and I know you
8 know this, Mr. DiGiovanni, and hopefully other counsel as
9 well, of my typical practice in this regard. It is probably
10 called out, I think, in citing to Vitronics, I believe, that
11 to the extent that extrinsic evidence will help the Court
12 understand the technology, I am willing to hear that. But I
13 am not going to hear extrinsic evidence today. I am just
14 raising that as a point so I don't have to field objections
15 or deal with efforts at presenting extrinsic evidence
16 outside of the dictionary context that may be offered to
17 help me understand the technology. I don't think I am going
18 to need that because I know I have able counsel here who are
19 going to do a good job of tutoring me on the chemistry
20 involved.

21 Any questions about that or concerns?

22 MR. CHAMBERS: Your Honor, we will present it
23 just so it covers intrinsic evidence.

24 THE COURT: That is what I am telling you to do,
25 unless you have an argument that you want to make to me --

1 Judge, there is cause for you to hear this and the cause is
2 that it's going to help you understand the technology.

3 MR. DiGIOVANNI: We did cite to some
4 dictionaries for one of the terms.

5 THE COURT: That is fine.

6 MR. DiGIOVANNI: And to one concurrent patent
7 with one of the other terms.

8 THE COURT: Are you going to have difficulty
9 with that?

10 MR. CHAMBERS: If they are going to bring in
11 patents outside the family, we will probably want to raise
12 an objection.

13 THE COURT: That is fine.

14 MR. CHAMBERS: And we will want to address it.

15 THE COURT: Unless offered within the context
16 that I just discussed, I won't accept that evidence.

17 MR. CHAMBERS: For that reason, Your Honor, I
18 won't bother to do it, since I am going to be going first.

19 THE COURT: Counsel.

20 MR. HANSEN: Your Honor, this seems related. We
21 have a few introductory slides that are depictions of some
22 of the molecules and a depiction of the pathway.

23 THE COURT: Those are demonstratives. Right?

24 MR. HANSEN: I want to make clear that is okay.

25 THE COURT: I am talking about evidence, not

1 demonstratives.

2 Any other housekeeping matters?

3 Here, we will do it term by term. I will give
4 the plaintiff the last word on a brief rebuttal to the
5 defendants' positions on the various terms.

6 MR. CHAMBERS: Your Honor, thank you.

7 MR. DiGIOVANNI: Your Honor, one additional
8 thing. I have conferred with my co-defendant's counsel, and
9 we have designated a lead person to take the argument for
10 each of the various terms.

11 THE COURT: Okay.

12 MR. DiGIOVANNI: The other party may have
13 something to add afterwards. So we have designated a lead
14 person. And in addition, Mr. Hansen is going to do a brief
15 technology tutorial.

16 THE COURT: Okay.

17 Are you asking me to find out whether the
18 plaintiff would have any objection to a little supplementing
19 to the lead's position?

20 MR. DiGIOVANNI: To the extent Your Honor finds
21 it objectionable -- the two defendants are separate. So I
22 thought Your Honor's practice was to allow each defendant
23 to --

24 THE COURT: You can. But if you designated a
25 lead as a timesaving device, that's great.

1 MR. DiGIOVANNI: I wanted to let you know, that
2 is what we have done.

3 THE COURT: So I don't have to hear repetitive
4 arguments.

5 MR. CHAMBERS: Our only objection would be if
6 they are repetitive -- there was a single brief that we were
7 responding to, that was a combined brief. If they are going
8 to be repetitive about some of these things, that would
9 trouble us.

10 THE COURT: That is fine. Just as in an
11 evidentiary proceeding, if you have objections, the fact of
12 the matter is that while we are not formally presenting
13 evidence, this Court is going to be asked to find some
14 facts, in spite of the de novo standard.

15 My little dig there.

16 Let's go, counsel.

17 MR. CHAMBERS: Thank you, Your Honor. Good
18 morning.

19 This invention at its most basic level is a
20 nutritional supplement that let's you work out longer with
21 less soreness.

22 THE COURT: Counsel, please don't be
23 disconcerted if from time to time I turn my attention to the
24 computer. I am listening.

25 MR. CHAMBERS: Yes, Your Honor.

1 The patents in suit use beta-alanine and
2 L-histidine, which are two amino acids. Amino acids are the
3 building blocks of peptides and proteins. Dipeptides have
4 two amino acid residues that are covalently joined.
5 Oligopeptides have a few amino acid residues covalently
6 joined. And polypeptides are many amino acid residues
7 covalently joined.

8 Because a dipeptide is two residues and a
9 tripeptide is three residues and a tetrapeptide is four
10 residues, sometimes a single residue is referred to as a
11 monopeptide.

12 Now, structurally, these are found on the next
13 slide, where we have one of the --

14 THE COURT: Did you bring binders?

15 MR. CHAMBERS: I am sorry. We did. I will be
16 happy to pass those up.

17 THE COURT: If you could provide us with two
18 copies.

19 MR. CHAMBERS: We see in this slide the key
20 molecule of this patent, which is beta-alanine. And
21 beta-alanine has an amino side and it has a hydroxyl side.
22 The patent also describes beta-alanine esters. And those
23 are, the beta-alanine when it's joined, it no longer has
24 this hydroxyl but instead it has an ester linkage.

25 It also talks about beta-alanine amides. That's

1 when it has an amino or an amide group here instead of this
2 hydroxyl.

3 When those are combined into a dipeptide, you
4 get the substance that is down in the lower corner, or lower
5 left-hand corner, and that's one of the molecules that's
6 also discussed in the patent. And you can see that in this
7 molecule, this dipeptide, the beta-alanine no longer is in
8 the same form as it was up here. It has lost a hydroxyl.
9 It is no longer a beta-alanine. Instead, it is a residue.
10 And the art calls it an amino acid residue rather than
11 calling it an amino acid.

12 Now, the prior art disclosed dipeptides, such as
13 this carnosine, used in the manner that the patents
14 described. But the prior art didn't describe using the
15 amino acids.

16 The inventors of the patent in suit invented a
17 way to avoid muscle fatigue by regulating the ion
18 concentration using the amino acids beta-alanine as well as
19 L-histidine. These are the residues of those two. And you
20 could regulate this using these amino acids rather than
21 dipeptides. It was already known that you could use
22 dipeptides. But the inventors discovered that using an
23 amino acid to accomplish this was more effective and more
24 efficient.

25 Now, in the original filing, the applicants set

1 forth a large number of embodiments. These embodiments are
2 claimed in the patents in suit and later issued patents.

3 Now, some of those later patents have claims
4 addressing dipeptides. But most of the claims of the
5 patents in suit are to the polypeptide -- I am sorry, most
6 of the patents in suit are to using the amino acid, not
7 using the residues as they would be found in the
8 polypeptide.

9 The patents in suit disclose three dipeptides:
10 carnosine, anserine, and balenine.

11 Plaintiffs say these dipeptides are not part of
12 the claim. Defendants say they are. That is one of the
13 basic issues for the Court to decide.

14 Now, the patents have seven terms. We are going
15 to talk today about the group of terms beta-alanine,
16 L-histidine, and active derivative.

17 The first term, of course, is beta-alanine. The
18 second is L-histidine. Active derivative is closely related
19 but it's intertwined because the claim says, an amino acid
20 or active derivative selected from the group consisting of
21 beta-alanine, an ester of beta-alanine, an amide of
22 beta-alanine. So the meaning of beta-alanine is going to
23 control what active derivative means in the claims at issue.

24 Beta-alanine is an amino acid. And both the
25 patents in suit as well as the defendants' expert indicate

1 that two amino acids react to form a dipeptide.

2 Defendants' position is that the claims in the
3 patent, where there is a reference to beta-alanine, it is a
4 reference to the amino acid and the dipeptide, oligopeptide,
5 or polypeptide. This is confusing and it contradicts the
6 intrinsic evidence.

7 Now, an important distinction that the Court has
8 to address is the fact that the dipeptide has within it the
9 covalently linked residues of two amino acids. But it would
10 be scientifically incorrect to say that the dipeptide
11 includes the two amino acids. Once the two amino acids
12 enter into this covalent bonding, that bond is formed and
13 the two individual amino acids no longer exist except as a
14 residue. Then you have the dipeptide.

15 It's much like an apple pie. Once you take the
16 apples, you cut them up, you put them into the crust and you
17 bake them, you end up with an apple pie. And the residue of
18 apples is in that apple pie. But the round apple, the
19 actual apple, is no longer in that apple pie.

20 If you went to the grocer, and you said, I would
21 like a bag of apples, and they brought you a bag of apple
22 pies, you would think there was some kind of a mistake.

23 Similarly, in a dipeptide, the two amino acids
24 no longer exist as amino acids but instead they exist as
25 residues. And you can see that in this particular slide,

1 here is what an amino acid is. And it's got this hydroxyl.
2 Here is what the dipeptide is. It no longer has the
3 hydroxyl. It is, as I said before, the residue.

4 Now, beta-alanine and L-histidine are two
5 well-known amino acids, and the Court should construe them
6 together, as we have already said. And because active
7 derivative is only used in the claims where the Markush
8 group of beta-alanine, amide of beta-alanine and ester of
9 beta-alanine, that Markush group and that active derivative
10 should be construed together.

11 The defendants have the belief that the term
12 beta-alanine should be beta-alanine, dipeptide, oligopeptide
13 or polypeptide. We call that ADOP. So when I refer to
14 ADOP, what I am trying to say is, all four of them together,
15 which is what the defendants are saying that the term
16 beta-alanine means.

17 Now, we find that there is strong evidence for
18 what the inventors meant and for what the examiner
19 understood in a petition to make special that was found in
20 the very first patent that was in this family. In the
21 petition to make special, it's necessary that you not only
22 explain the prior art, but you explain why that prior art
23 does not stop the patentability of your claims. That's what
24 is required by the Patent Office for a petition to make
25 special.

1 Now, the inventors made clear that when they
2 referred to beta-alanine or L-histidine in the claims, that
3 they meant the individual amino acids.

4 If I can show you, this is found at JA73, and it
5 is from the petition to make special in that the applicants,
6 the inventors said something very interesting. They are
7 talking about the references --

8 THE COURT: Could you blow that up a little bit,
9 counsel.

10 MR. CHAMBERS: I will certainly try.

11 THE COURT: These are backup glasses. I lost my
12 originals.

13 MR. CHAMBERS: How about that. If I can get my
14 left and right proper, I will be fine.

15 They are talking about the prior art. They are
16 talking about the Setra reference. They say it describes
17 compositions containing the carnosine dipeptide that I
18 showed us just a minute ago, and it uses that composition
19 for treating muscle fatigue in athletic performance. It
20 says carnosine is a dipeptide. Of course, right there is
21 what the dipeptide would actually be called scientifically,
22 beta-alanyl L-histidine.

23 According to the Setra invention, they say that
24 dipeptides contain histidine, containing that ring structure
25 that is on the histidine ring, so that's on the histidine

1 that I showed you, can be used for these benefits. And
2 then, on the very next page, they say, "In contrast to the
3 present invention, the compositions and methods described in
4 Setra's invention teach dipeptides."

5 Well, that, we believe, means that the present
6 invention does not include dipeptides. I don't see any
7 other way you could read that.

8 Now, it goes on to say -- so we have got a
9 disclaimer at Part 1, where they say, In contrast to the
10 present invention. Now in the next sentence, it says, "In
11 the present invention," then it uses those terms that we are
12 going to be fighting over, beta-alanine and L-histidine,
13 "are administered to regulate hydronium ions." And then it
14 says, Setra does not teach or suggest or mention using
15 mono peptides for the treatment of hydronium ions. We
16 believe that mono peptide is referring to the two
17 mono peptides that are set forth right above that.

18 That is a second time they disclaim the idea
19 that the term beta-alanine and L-histidine is really ADOP.

20 If you look at the bottom, you find that Harris,
21 et al., also described the effect of using dipeptides. Then
22 they define what the dipeptides are, carnosine and anserine
23 on the hydronium ion concentrations in muscle.

24 Then it distinguishes Harris from their
25 invention by saying, Harris neither teaches nor suggests the

1 use of beta-alanine or L-histidine, i.e., that is,
2 mono peptides in the regulation. They are showing that in
3 their invention we are using the mono peptides. In Harris,
4 they were using the dipeptides.

5 So the first statement, where it says Harris
6 described the effect of dipeptides on hydronium ion
7 concentrations in muscle, they are distinguishing it yet a
8 third time, disclaiming that theirs is the same thing. And
9 then in the fourth position, when they say i.e.,
10 mono peptides, they are saying, we are defining alanine and
11 histidine as mono peptides.

12 You also find on that same page, when they are
13 talking about the histidine reference, they are talking once
14 again, in histidine, of using beta-alanine and carnosine.
15 Carnosine is a dipeptide. So they are saying, we see a
16 difference between beta-alanine and the dipeptide side. And
17 then they are saying that the present invention teaches that
18 the administration of beta-alanine, either alone or in
19 combination with other factors, is useful in reducing
20 hydronium ion concentration.

21 That is even an additional time.

22 What we find is that at least four times in that
23 particular passage they have said that beta-alanine and
24 L-histidine are the mono peptides, not the dipeptides. That
25 petition goes on and says none of the references either

1 alone or in combination teach or suggest a method of
2 regulating hydronium ion concentrations by administering
3 beta-alanine to a human tissue.

4 Your Honor, if beta-alanine really meant
5 dipeptides, it's clear that the Setra reference, which is
6 dealing with looking at dipeptides, would have invalidated
7 any possible claims. So we don't believe that it is meant
8 to include those dipeptides.

9 Once again, Your Honor, that means four times in
10 four separate places on JA74 the applicants disclaimed the
11 definition that defendants are now proposing. Setra,
12 Harris, saying the beta-alanine an L-histidine are
13 mono peptides in contrast to Setra, et cetera, and in the NS
14 or i.e. for Harris.

15 Most importantly, the Court has to consider how
16 the claims of the patent could issue covering dipeptides
17 with Setra and Harris there. The prior art would explicitly
18 and inherently anticipate the invention. So it is not clear
19 how the examiner could have been construing the claims in
20 the way that defendants now claim.

21 If you look at JX-9, Exhibit 9, at JA96 through
22 97, that is the Setra patent application. And that Setra
23 patent application shows a couple things. It shows that
24 they are using the dipeptides and it shows in the claim,
25 Claim 5 of Setra, that they are using it for muscle fatigue,

1 which is exactly what the patents in suit are dealing with.

2 Table 4 in the patents in suit, which is found
3 in Exhibit 3, Column 11, separately considers beta-alanine
4 and the dipeptide, indicating that beta-alanine for the
5 inventors was something different than the dipeptide. You
6 can see in the bottom, where they are talking about
7 beta-alanine, beta-alanine, beta-alanine, beta-alanine. And
8 then over here they talk about carnosine, indicating that
9 they saw beta-alanine as something different than the
10 dipeptide carnosine.

11 Now, in describing the different embodiments of
12 the invention, the specification says that beta-alanine can
13 be provided as an amino acid or as a component of
14 dipeptides, oligopeptides or polypeptides. It doesn't say
15 that beta-alanine is. But it is a component. And it
16 indicates that the amino acids are something very different
17 than the dipeptides.

18 This is also true for the claims.

19 Considering Claims 1 through 4 of the '098
20 patent, which is at Exhibit 2 of the joint appendix at 43,
21 here the applicants specifically call for a peptide source,
22 including beta-alanine. Now, if beta-alanine means ADOP,
23 then it really makes no sense, because then the claim is
24 saying, a peptide source of polypeptides. That is not the
25 way scientists normally speak.

1 When the applicants call for beta-alanine, they
2 mean the amino acid in these claims, and unless they clearly
3 say something else, such as a peptide source, it should be
4 construed as the amino acid.

5 The specification also underscores the need to
6 supply beta-alanine as an amino acid and not as a component
7 of the dipeptide. We will talk about that a little later in
8 the construction. And the examples disclosed in the
9 specification show the preferred embodiments were the
10 individual amino acids.

11 Now, active derivative is part of a larger
12 element of the claim, which is, a composition comprising an
13 amino acid or an active derivative thereof selected from the
14 group consisting of beta-alanine, an ester of beta-alanine
15 and an amide of beta-alanine. And you can see that on the
16 exhibits, Exhibit 3, looking at Claims 5, 17 and 33.

17 The Court only needs to define active derivative
18 in the context that it's used in the claim. An active
19 derivative is defined in the patent as a compound derived
20 from or a precursor of the substance that performs in the
21 same or similar way in the body as the substance in the
22 body.

23 Examples include esters and amides.

24 You can find that particular reference there at
25 Column 2, Lines 46 through 50. The patent indicates -- I am

1 sorry, Exhibit 3, one of the patents in suit, shows that in
2 Column 2, Lines 31 through 34, and also Column 5, Lines 11
3 through 14, what a precursor is. It talks about
4 beta-alanine and L-histidine being precursors to the
5 dipeptide, not the other way around. Because a claim term
6 can't be construed in isolation, that is why it is necessary
7 to put these particular items together.

8 Basically, a precursor is something that comes
9 before. If you think of the amino acids as building blocks
10 for peptides and building blocks for proteins, then you can
11 have the individual amino acids and they form the peptides.
12 And they are precursors of the peptides. But you wouldn't
13 normally say that the peptides are the precursors to the
14 amino acid. And here is why.

15 Just like a brick, a brick is a precursor to a
16 brick wall, you don't consider a brick wall as a precursor
17 to a brick. You don't tear down a brick wall in order to
18 make bricks. It's something entirely different.

19 Now, as I said before, defendants want this
20 construction to have ADOP, amino acid dipeptide,
21 oligopeptide and polypeptide, every time the word
22 beta-alanine appears in the claims. The intrinsic record,
23 however, shows what that term, an amino acid or active
24 derivative from the group consisting of beta-alanine, an
25 ester of beta-alanine, and an amide of beta-alanine, they

1 show what that means.

2 The term active derivative is an active
3 derivative of an amino acid and it's not an active
4 derivative of the oligopeptide or polypeptide or the
5 dipeptide. An amino acid is not a dipeptide, which is by
6 definition two amino acid residues that are chemically
7 bonded with a peptide bond between them.

8 I have already spoken that beta-alanine and
9 L-histidine are precursors and it's not ADOP, as suggested
10 by defendants. But in addition, the dipeptides of
11 beta-alanine and L-histidine don't even perform in the same
12 or similar way in the body as the individual amino acids.

13 And the patent sets forth that. That is
14 important because active derivative, that is a key element
15 of that. For example, the patents in suit say that the
16 dipeptides help in the buffering capacity of the muscles
17 during periods of sustained exercise, whereas the amino
18 acids do not. That can be found at Exhibit 3, Column 2,
19 Lines 1 through 23, Column 4, Line 66, through Column 5,
20 Line 10. Also, the dipeptides have to be synthesized inside
21 the muscle cell from the precursor amino acids, beta-alanine
22 and L-histidine. That is at Column 5, Lines 11 through 29.
23 The dipeptides don't fit within the meaning of an active
24 derivative. And that is set forth in the patents in suit as
25 well as the claims that you have.

1 Now, the term active derivative should be
2 construed to mean a compound derived from or a precursor of
3 the substance that performs in the same or similar way in
4 the body as the substance or which is processed into the
5 substance and placed into the body.

6 The term active derivative first appears in
7 newly added claims. And the applicants set forth the
8 support for these claims. Exhibit 5 at JA83 says that.
9 When you are filing something in the Patent Office, you
10 can't just file anything you want, any words you want. You
11 have to say where the support for those terms are. So we
12 can actually look for the support for those terms and see
13 what they meant.

14 To support these newly added claims, the
15 applicant pointed to Figures 3 through 6 and Example 1. And
16 that is found, where they describe this, at Exhibit 5, JA83,
17 but it is also found in Exhibits 1 through 3 because you can
18 find Example 1 and you can also find Figures 3 to 6 where
19 they describe them.

20 A review of those figures in Example 1 show that
21 feeding studies that support the claim that you later find
22 are feeding studies of the amino acid beta-alanine, but not
23 feeding studies dealing with the dipeptide, the oligopeptide
24 or the polypeptide.

25 Now, if this term really meant ADOP, as

1 defendants would have us believe, then the applicants would
2 have needed to show support for feeding the dipeptide,
3 support for feeding the oligopeptides, and support for
4 feeding the polypeptides in order to get the effect that you
5 find in the claims.

6 In addition, the word beta-alanine, if the word
7 beta-alanine really meant ADOP, then where are those
8 beta-alanine esters and where are those beta-alanine amides
9 of the dipeptides?

10 They are not in the specification. The
11 specification is silent on amides and esters that are
12 dipeptides. Where are the beta-alanine esters and
13 beta-alanine amides of the oligopeptides, and where are the
14 beta-alanine esters and beta-alanine amides of the
15 polypeptides in the specification? There are none.

16 Now, there is no place in the specification that
17 describes any polypeptide ester, a beta-alanine, or any
18 oligopeptide ester of beta-alanine or even any dipeptide
19 esters of beta-alanine.

20 There is a reason for that.

21 Remember that slide that we saw earlier. This
22 is what the dipeptide looks like. This is what the
23 beta-alanine looks like. And this is what the ester looks
24 like.

25 You can see that the ester has an oxygen bond

1 here, whereas the dipeptide has a nitrogen bond. You are
2 going to have to destroy the beta-alanine dipeptide in order
3 to have an ester. You wouldn't have a dipeptide anymore.
4 So we don't believe that this term includes esters of the
5 dipeptides, esters of the oligopeptides, and esters of the
6 polypeptides, because there doesn't seem to be support in
7 the specification as filed.

8 L-histidine is another amino acid that is
9 important in this invention. For the same reasons described
10 previously for beta-alanine, we think it should be held to
11 be the same. For that reason, we believe that the
12 constructions that we have provided, that we talked about
13 earlier, should be the constructions that the Court adopts.

14 And it's my understanding that the way you
15 wanted to do this is that the defendants would now go
16 forward with their analysis, and then we will come back to
17 dietary supplement.

18 THE COURT: That is what the parties agreed
19 upon. Right? Term by term?

20 MR. CHAMBERS: Yes.

21 THE COURT: We grouped the first ones.

22 MR. CHAMBERS: Yes. Thank you.

23 MR. HANSEN: May I approach, Your Honor, and
24 give you a copy?

25 THE COURT: Yes.

1 MR. HANSEN: May I proceed?

2 THE COURT: Yes.

3 MR. HANSEN: Thank you, Your Honor.

4 As we said, I am going to present a brief
5 tutorial before Mr. DiGiovanni takes the lead argument on
6 the terms that we are addressing now.

7 This is the first slide. What we want to do
8 here is accomplish two things for the Court. Some of this
9 will look a little similar to what plaintiffs presented but
10 the emphasis is going to be different. We want to
11 graphically show the structures of some of these compounds
12 to give the Court an idea of the similarities and
13 dissimilarities between the compounds in a visual way, since
14 that's not done in the patent.

15 The other thing we wanted to do was to discuss
16 the metabolic pathway by which these materials, be it the
17 dipeptide form of beta-alanine or the single amino acid form
18 of beta-alanine, are processed in the body, because one
19 issue that is going to be of particular importance in
20 construing these claims and understanding what a portion of
21 the specification is talking about is being sure that the
22 Court is aware of where we are in the metabolic process.

23 The reason I say that is because some of the
24 claim limitations speak to certain compounds at a certain
25 location, for example, in the blood or blood plasma, or in

1 the muscle tissue, or at the point of initial delivery. And
2 what the patent teaches about whether a single peptide or a
3 dipeptide is used depends largely on where we are in the
4 metabolic process. So we thought that might be helpful.

5 So here we are. These are two main single amino
6 acid forms of the key compounds in these claims,
7 beta-alanine and L-histidine, both of which are naturally
8 occurring amino acids.

9 By way of explanation, this term amino acid, we
10 thought we would explain what we are talking about when we
11 use that, since it's a large category, actually, of
12 compounds in nature. Amino acids are defined by an acid
13 group here, which has a carbon, doubly bonded to an oxygen,
14 and then a hydroxyl group, which is an oxygen bonded to a
15 hydrogen. That is the acid part of the amino acid.

16 If you look, you can see beta-alanine has one of
17 those and L-histidine on the right also has one of those.
18 The other defining feature of an amino acid is an amine
19 group. That is a nitrogen bonded to two hydrogens. You can
20 see that beta-alanine has one here and L-histidine has one
21 here.

22 So these are the defining features that make
23 these two compounds amino acids.

24 All right. So we are obviously going to hear a
25 little bit about carnosine today, and we already have.

1 Carnosine is a dipeptide. You can see that the
2 structures of beta-alanine and L-histidine are preserved in
3 the dipeptide save for one location, that location is right
4 here. When these two molecules bond, the hydroxyl group
5 that was present here is lost and this carbon bonds to the
6 amine group here. And what happens is you give off a water
7 molecule.

8 But you can see that the identities of these
9 molecules are preserved. So this molecule can then be
10 reverse-broken-down to provide the single amino acid.

11 Also, one thing to be mindful of, you will see
12 in the patents there is a tendency to jump between common
13 names and the formal chemical names. So carnosine will
14 sometimes be referred to as beta-alanyl L-histidine.

15 In the patents, the goal is to produce more of
16 this beta-alanyl L-histidine in the muscle tissue. That is
17 the ultimate goal that produces this hydronium ion
18 regulation effect.

19 The patents also speak of other dipeptide forms
20 of beta-alanine. One of them is called anserine, that is
21 here. The formal name is beta-alanyl L-1-methylhistidine.
22 We can see again that the structure of beta-alanine is
23 preserved, save for this peptide bond, one location. And
24 the histidine structure is present here as well, except
25 there is this little extra group here, a carbon and three

1 hydrogens, that is called a methyl group. Sometimes you
2 will hear anserine referred to as including a methylated
3 analog of histidine, and that refers simple to the fact that
4 there is this methyl group sticking out on the histidine
5 molecule.

6 Similarly, we have balenine down here. Again,
7 here is the beta-alanine component, just a single peptide
8 bond between the two molecules. Again, this is a methylated
9 analog of histidine, so it has this CH-3 group, carbon and
10 three hydrogens sticking out.

11 Also, one thing to note here is that even after
12 the dipeptide is formed, it still retains the essential
13 features of an amino acid. So if we look at anserine, here
14 is an amine group, here is the acid group. If we look at
15 balenine, here is the acid group, here is the amine group.

16 What does that mean? That means these molecules
17 can continue linking to other amino acids and that's how you
18 get an oligopeptide or a polypeptide, by that continual
19 linkage. When you hear about proteins, proteins are very
20 long chains of these types of amino acids.

21 With this background in mind, let's talk a
22 little bit about the metabolic pathway. We thought it might
23 be helpful to have a little illustration of it.

24 In this example, we are just talking about
25 ingestion. But the patent goes into other methods of

1 delivery.

2 A person, it is taught in the patents, can
3 ingest beta-alanine in its single amino acid form or in its
4 dipeptide form. I realize the parties are arguing about
5 what beta-alanine means. At this level of teaching it is in
6 the patent and it was in the Setra patent that plaintiffs'
7 counsel discussed.

8 Okay. If carnosine is ingested, what happens is
9 in the digestive tract it is broken down into the
10 constituent amino acids. Here is the beta-alanine, two of
11 the constituents single have to form, here is the
12 beta-alanine and here is the L-histidine. That is what
13 happens in the blood. There is actually, in one of the
14 examples, Example 2 in the patents, where they actually used
15 carnosine, when they tested the blood, the carnosine was
16 gone in the blood. What was left was just a single amino
17 acid form. So there is a conversion process that takes
18 place when you ingest carnosine. But at the blood, it is a
19 single amino acid form.

20 The next part of the metabolic pathway that is
21 taught in the patents is to, in the muscle tissue, then,
22 synthesize carnosine by recombining the beta-alanine and the
23 L-histidine.

24 So again, as this is intended to illustrate, we
25 have really three key locations to consider when we are

1 talking about what chemicals are at issue in the metabolic
2 pathway. Are we at the point of ingestion? Are we in the
3 blood or blood plasma? Or are we in the muscle tissue?

4 It helps to have an illustration like this to
5 try to keep those issues straight.

6 Unless the Court has any questions about this, I
7 will defer to Mr. DiGiovanni for the argument.

8 THE COURT: Thank you, counsel.

9 MR. DiGIOVANNI: Your Honor, may I approach the
10 easel?

11 THE COURT: Sure.

12 MR. DiGIOVANNI: Thank you.

13 Can Your Honor read this?

14 THE COURT: Yes, I can.

15 MR. DiGIOVANNI: Okay. Terrific. Thank you,
16 Your Honor.

17 So the first terms we are going to address are
18 beta-alanine and L-histidine, and immediately after that I
19 will address active derivative.

20 So with regard to beta-alanine and L-histidine,
21 these are terms that were expressly defined by the inventors
22 in the patents. And what we did not see was the definition
23 that was attributed to these terms by the inventors in the
24 earlier presentation. But I am going to certainly address
25 that.

1 What I have done is, on the easel, I have the
2 two parties', the plaintiffs' and defendants' constructions
3 that we will be referring to. And plaintiffs' construction
4 is on the right-hand side, and defendants' construction is a
5 little bit different than how it was characterized earlier.

6 What defendants are arguing, and based on the
7 inventors' definitions, is that beta-alanine means
8 beta-alanine in the form of the individual amino acid or as
9 a component of the dipeptide, such as carnosine or an
10 oligopeptide or a polypeptide or an active derivative
11 thereof.

12 The L-histidine definition is very similar, just
13 as the inventors set forth. That is, L-histidine means
14 L-histidine in the form of the individual amino acid by
15 itself, or as a component of a dipeptide, or an oligopeptide
16 or a polypeptide.

17 So what I think we heard in the earlier
18 presentation from plaintiffs is that defendants contend that
19 beta-alanine means the entire dipeptide. That is not what
20 is being contended. Beta-alanine means the beta-alanine,
21 either in the individual form or as a component of the
22 dipeptide, as we saw in the technology tutorial.

23 So, Your Honor, these slides, I am going to skip
24 a few that would be redundant after the plaintiffs'
25 presentation. Just as a little bit of background.

1 Representative Claims 32 and 33 just show how beta-alanine
2 and L-histidine are used in the claims. 32 says a human
3 dietary supplement comprising beta-alanine and L-histidine.

4 So the issue to be addressed here is, well, what
5 did the applicants mean when they said beta-alanine? And
6 what did they mean when they said L-histidine?

7 This next slide, Your Honor, is a direct quote
8 in the box there from the '361 patent. The three patents in
9 suit have the same specification, so it's in all the patents
10 in suit.

11 What the inventors said in their application,
12 and I will read the highlighted portion, they say, Each of
13 the beta-alanine or L-histidine can be the individual amino
14 acids or components of dipeptides, oligopeptides or
15 polypeptides.

16 That is, Your Honor, directly quoted in
17 defendants' construction.

18 The plaintiffs, on the other hand, are seeking
19 to contravene that construction. In fact, seeking to
20 directly contravene the inventors' definitions by, in fact,
21 striking out or removing something the inventors expressly
22 said. The inventors expressly said that L-histidine and
23 beta-alanine can be components of dipeptides. And what we
24 are seeing is plaintiffs are seeking to avoid that, even
25 though it was a direct statement by the inventors.

1 So what's important about this slide and the
2 definition is, of course, the inventors are acting as their
3 own lexicographers, as they are allowed to do. And, in
4 fact, under Phillips, as Your Honor knows, the Federal
5 Circuit says that the inventors' lexicography governs.

6 Now, below that quotation is just a couple of
7 bullet points summarizing sort of the importance of the
8 definition of the inventors. Number one, it refers to
9 beta-alanine and L-histidine in either the individual amino
10 acid form or as components of dipeptides, oligopeptides or
11 polypeptides. And number two, as highlighted in green in
12 that definition, the beta-alanine or L-histidine can be
13 active derivatives.

14 So if you take the highlighted portion in both
15 yellow and green, that is exactly defendants' claim
16 construction proposal in this case. It is directly from the
17 patent. So the fact that there is a definition was admitted
18 by plaintiffs. They conceded that in their opening brief.
19 The plaintiffs state, this is a quote from their opening
20 brief, they talk about what the inventors were stating, and
21 they say, as they did in their argument, they immediately
22 went to the prosecution history to say that it modifies the
23 definition of beta-alanine and L-histidine in the
24 specification.

25 So there appears to be no dispute, there was no

1 dispute, Your Honor, in the opening brief that, in fact,
2 there was a definition set forth. I believe in the
3 answering brief they tried to step back from that a bit and
4 say there were multiple definitions in the patent
5 specification. They mentioned that actually in their
6 opening brief and again in their answering brief. But
7 taking a look at the inventors' definitions, there are no
8 multiple definitions set forth in there. There is a single
9 definition of beta-alanine and L-histidine, and that's what
10 defendants have adopted as their proposed constructions in
11 this case.

12 Moving away from the express definition of the
13 inventors and looking at the remainder of the patent
14 specification, which again is the same in all three patents,
15 the background of the invention section is quoted in this
16 slide. And here, the inventors state, Dipeptides of
17 beta-alanine and L-histidine and their methylated analogs
18 include carnosine, anserine, balenine. Here the inventors
19 are expressing their view that is consistent with their
20 definition that, in fact, beta-alanine is part of a
21 dipeptide and is part of carnosine.

22 They are not saying that carnosine includes some
23 sort of residue that you would consider not beta-alanine.
24 Here they are calling it beta-alanine. They are using the
25 term beta-alanine to mean a portion of the dipeptide.

1 Here is a similar statement made by the
2 inventors in the context of Example 2 in the patents, where
3 the phrase beta-alanine is used by the inventors, in the
4 parentheses, they say, "(e.g., in the form of anserine and
5 carnosine.)

6 Once again, the inventors are expressing their
7 clear view that was set forth in their definition that, in
8 fact, beta-alanine can exist in the form of a component of
9 carnosine. In other words, beta-alanine is not limited
10 solely to the individual amino acid, because when you have
11 carnosine you have a beta-alanine component of that
12 molecule.

13 Once again, here is Table 4, summarizing some
14 experiments, an absorption study that was performed by the
15 inventors. They used as some of their test material not
16 only beta-alanine, the individual amino acid, but they also
17 used carnosine and they also used a chicken broth. And for
18 both carnosine and chicken broth, the inventors referenced
19 that as having beta-alanine.

20 That was the specification, Your Honor.

21 I am going to move to the claims, in fact, most
22 specifically, the claims of the '361 patent, to see how the
23 inventors used the term beta-alanine and L-histidine.

24 Now, what's quoted here are Claims 1 and 3 of
25 the '361 patent.

1 Here we have Claim 1, which is a fairly general
2 claim, stating, claiming a composition comprising a mixture
3 of creatine and a composition comprising an amino acid or
4 active derivative thereof selected from the group consisting
5 of beta-alanine, an ester of beta-alanine, and an amide of
6 beta-alanine.

7 Now, Claim 3 is critical. In Claim 3, a
8 dependent claim, the inventors claimed a composition of
9 Claim 1 wherein the beta-alanine further comprises a
10 dipeptide, an oligopeptide or a polypeptide.

11 So in Claim 3, Your Honor, of the '361 patent,
12 there is an express use of the term beta-alanine that must
13 include beta-alanine as a component of a dipeptide or a
14 polypeptide or an oligopeptide.

15 The definition proposed by plaintiffs just
16 doesn't fit in this claim. It would not work. I have a
17 couple of slides that follow that explain.

18 This next series of slides explains the dilemma
19 that is posed to plaintiffs due to Claim 3, and perhaps
20 that's why we haven't heard anything about Claim 3 yet, Your
21 Honor. What we see in Claim 3 is the use of beta-alanine --
22 let me just back up.

23 In Claim 1, beta-alanine has its definition as
24 expressed by the inventors. So that means it can be either
25 the individual amino acid or a component of a dipeptide.

1 Then Claim 3 narrows Claim 1 and expresses that
2 their beta-alanine further comprises a dipeptide, an
3 oligopeptide or a polypeptide. And this Claim 3 only makes
4 sense if the inventors' definition of beta-alanine is
5 adopted, which is the same definition that is being offered
6 by defendants.

7 Plaintiffs' doesn't work.

8 So in the bottom left here, under defendants'
9 construction of beta-alanine, Claim 1 means that
10 beta-alanine can exist in the individual form or as a
11 component of a dipeptide. And Claim 3 narrows the claim and
12 specifies that the beta-alanine of that claim exists as a
13 component of the dipeptide, or the oligopeptide or the
14 polypeptide.

15 Let me go over to the bottom right, using
16 plaintiffs' construction. So if you adopt plaintiffs'
17 construction, Claim 1, or any time you use beta-alanine
18 precludes the beta-alanine from existing in the form of a
19 component of the dipeptide. Now you go to Claim 3 under
20 plaintiffs' construction, there is no way to reconcile Claim
21 3 under plaintiffs' claim construction, because their
22 construction mandates that the beta-alanine exists by itself
23 as an individual amino acid.

24 So you can't have a situation where the
25 beta-alanine further comprises a dipeptide, oligopeptide or

1 polypeptide.

2 So, again, on this Claim 3 dilemma of
3 plaintiffs, if you adopt their claim construction -- and
4 this is an exercise where I placed in their construction in
5 brackets in Claim 3, where the term beta-alanine existed --
6 it's the composition of Claim 1 wherein the individual amino
7 acid, beta-alanine, or its salt, ester, or amide, further
8 comprises a dipeptide, an oligopeptide or a polypeptide.

9 It's a complete impossible and nonsensical
10 claim, because if the beta-alanine further comprises the
11 dipeptide, it would no longer be an individual amino acid,
12 and therefore it would no longer be beta-alanine. It
13 collapses upon itself, Your Honor. It can't be read using
14 their construction.

15 So Claim 3 is irreconcilably inconsistent with
16 their construction.

17 Then the final slide on this summarizes that
18 there are essentially three problems that plaintiffs
19 encounter due to Claim 3 and due to their construction that
20 is different than the inventors' definition. That is,
21 number one, the construction is directly inconsistent with
22 Claim 3's requirement that the beta-alanine exists as a
23 component of dipeptide. No. 2, Claim 3 -- by the way, Claim
24 3 isn't the only claim that adopts that language. There is
25 also Claims 12 and 24 that also require that the

1 beta-alanine further comprises a dipeptide, an oligopeptide
2 or polypeptide.

3 Point 2 is Claim 3, 12 and 24 are rendered
4 nonsensical, contrary to Federal Circuit law.

5 And also, Claim 3, which is a dependent claim on
6 Claim 1, under defendants', under our construction, it
7 narrows Claim 1. Under plaintiffs' construction, it does
8 not narrow -- if it can be read to make any sense, which I
9 don't think it can, it certainly would not narrow Claim 1.

10 One additional point is, Claim 3 of the '361
11 patent, and Claims 12 and 24, they were added during the
12 prosecution of the '361 patent. The petition to make
13 special in the prosecution history we heard quite a bit
14 about. That was in the prosecution of the '596 patent,
15 which was an earlier patent. The '361 patent application
16 was filed later. And during the '361 patent application,
17 the inventors proposed to the Patent Office these new
18 claims, Claim 3 that I just talked about quite a bit, and
19 Claims 12 and 24. When they did that, as Mr. Chambers said,
20 typically, support is described for those new claims. And
21 what the inventors did in this case, when they adopted this
22 new Claim 3, 12 and 24, when they proposed it to the Patent
23 Office, they said, support for these new claims directed to
24 a composition where beta-alanine further comprises a
25 dipeptide, an oligopeptide or a polypeptide can be found,

1 inter alia, on Page 3, Line 28 to Page 4, Line 2.

2 That passage, that is the inventors' definition
3 in the original patent application and in the patent as
4 issued of beta-alanine and L-histidine, which is the
5 proposed construction that defendants are making.

6 Even after this petition to make special in the
7 prosecution history, the inventors proposed this Claim 3 and
8 re-incorporated this definition of beta-alanine, that would
9 allow beta-alanine to exist as either the individual amino
10 acid or as the component of a dipeptide or a polypeptide or
11 an oligopeptide.

12 THE COURT: Mr. DiGiovanni, are we, with these
13 claim terms, are we in that portion of the parties'
14 arguments over disclaimer and/or lexicography? Two
15 different concepts. I think the defendants assert they
16 acted as their own lexicographers, which they are entitled
17 to do, and this is how they define the term, you offer this
18 as further support for that.

19 Genentech is cited by both parties, one as being
20 apposite and the other, you, being inapposite. So is it the
21 defendants' position that this Court should say, you acted
22 as your own lexicographer and you are stuck with the
23 definitions that you gave to the PTO? Or am I misperceiving
24 the argument?

25 MR. DiGIOVANNI: No, Your Honor. We are saying

1 that the inventors proposed a definition and that definition
2 should govern.

3 I will address in just a moment the petition to
4 make special in the prosecution history. What our position
5 is, we recognize the prosecution history. We understand
6 that they made some statements. However, it was not clear,
7 it was not unmistakable. And the prosecution history as a
8 whole does not overcome the definition in the patent and
9 especially since, in these particular patents, patent claims
10 of the '361 application that we just looked at, they
11 referred back to that original definition, after this
12 prosecution history.

13 That is all part of the prosecution history.

14 THE COURT: So, then, you would say that this
15 portion of Genentech, that I should apply it as you suggest,
16 I am quoting from the case, where the Federal Circuit wrote,
17 I guess this is at, probably at Page 1564, I think.
18 Headnote -- I have the West version, Headnote 6, I think it
19 is, in discussing the prosecution history, the Court wrote,
20 "An appropriate method for resolving the issue is to avoid
21 those definitions upon which the PTO could not reasonably
22 have relied when it issued the patent."

23 That's the tool that I am told to utilize, is it
24 not, when issues of this type arise? Do I need to get into
25 that? Go ahead.

1 MR. DiGIOVANNI: I would say, Your Honor, that,
2 Genentech may apply.

3 THE COURT: I am not sure.

4 MR. DiGIOVANNI: I am saying, in a situation
5 where there is a definition that makes no sense in the
6 context of the patent claims, perhaps Genentech would apply.
7 Here, it's actually the opposite. It's the definition
8 that's being proposed by plaintiffs that can't be reconciled
9 with the patent claims that must be rejected.

10 So this is a brief timeline. I am not going to
11 go through this. This just indicates, Your Honor, in the
12 bottom left, the petition to make special was filed in March
13 of 1999. The '361 patent was filed in early -- January 9th,
14 2001, so when they reincorporated that definition, after
15 this petition to make special, it was a year and a half to
16 two years after that.

17 So the petition to make special, Your Honor
18 anticipated I was going to address this next, the petition
19 to make special that was filed in the '596 prosecution
20 history is not a disclaimer of the scope of the term
21 beta-alanine or L-histidine, for three reasons that I will
22 detail in the following slides.

23 Number one, it is not a clear and unmistakable
24 disavowal, which is what is required, as Your Honor knows.

25 No. 2, the prosecution history as a whole

1 indicates that it is not a disclaimer. The Federal Circuit
2 instructs that one is not to look at specific items in the
3 prosecution history without looking at the entirety.

4 And No. 3, the prosecution history of later
5 applications indicates very clearly that the applicants did
6 not disclaim beta-alanine as components of dipeptides or
7 polypeptides.

8 So number one, the petition to make special is
9 not a disclaimer.

10 A portion of the petition to make special that
11 was not referenced in Mr. Chambers's presentation appears at
12 Page 3 in joint appendix Exhibit 4. There the applicants
13 state that the methods of the present invention include
14 providing the dipeptides, peptides, or peptide analogs by
15 any number of means, including, for example, ingestion or
16 injection.

17 So this is an indication that, in fact, the
18 applicants did not disclaim, as is claimed by plaintiffs,
19 dipeptides in the invention to beta-alanine as components of
20 the dipeptides.

21 The portion of the petition to make special that
22 was cited by plaintiffs in their presentation is not a clear
23 and unmistakable disavowal. In it the applicants described
24 the Setra prior art reference, and, Your Honor, at most, the
25 applicants stated that Setra did not recognize the role of

1 beta-alanine or L-histidine either in the individual form or
2 the form components of the dipeptides.

3 So the focus, in other words, that the
4 applicants were pointing their finger at Setra and saying,
5 well, they didn't focus on the individual amino acids either
6 by themselves or as part of the dipeptides. Setra instead
7 just focused on the entire dipeptide.

8 So the statements that are made, then, in the
9 petition to make special, especially considering the fact
10 that there was an express definition in the patent
11 application of beta-alanine and L-histidine, that clearly
12 and expressly allowed beta-alanine to exist in the form of a
13 component of dipeptide, the statements that are made in the
14 petition to make special don't rise to the level of being a
15 clear and unmistakable disavowal of claim scope.

16 The next slide just is a cite to a case. I will
17 move on from that. I will move on, Your Honor. I am sorry.

18 The 3M case says that when the patentee has
19 expressly defined a term in the specification, that the
20 definition would control over broad remarks during
21 prosecution.

22 So this next slide makes the statement or
23 follows up on my earlier bullet point that the prosecution
24 history as a whole indicates there is no disclaimer.

25 So what do we look at when we look at the

1 prosecution history as a whole? Sure, we do look at the
2 petition to make special. We need to look at the entirety
3 of it, including the earlier portion of it that I cited,
4 which makes express reference to dipeptides. But you also
5 have to look at the '361 prosecution history, where the
6 applicants claimed the beta-alanine as part of the dipeptide
7 in Claims 3, 12 and 24, and then as I stated earlier, when
8 they did that they reincorporated that general definition,
9 even after the petition to make special.

10 Now, the prosecution of later patent
11 applications also shows no disclaimer. The broad statement
12 that was made by plaintiffs in their --

13 MR. CHAMBERS: Your Honor, are we going to go
14 into extrinsic evidence at this point? It appears that we
15 are.

16 MR. DiGIOVANNI: Your Honor, whether subsequent
17 patent applications are extrinsic or intrinsic, I don't
18 believe there has been a definitive ruling on whether they
19 are or not. I can't conclusively say this is extrinsic
20 evidence, Your Honor. This is the subsequent prosecution
21 history.

22 THE COURT: I think the point made earlier by
23 Mr. Chambers was his view is unless it's from the same
24 family --

25 MR. CHAMBERS: That is correct.

1 THE COURT: -- it would be appropriately viewed
2 to be extrinsic. Why would you disagree with that?

3 MR. DiGIOVANNI: This is the same family.

4 THE COURT: This is from the same family.

5 MR. DiGIOVANNI: So what we have here is the
6 '084 patent, which is a continuation-in-part application
7 from the same patent family. The broad statement made by
8 plaintiffs is that based on this statement in the petition
9 to make special that the applicants disclaimed dipeptides.
10 And they say that throughout their briefs.

11 In fact, they said it earlier today.

12 When they filed this continuation-in-part
13 application in the '084 patent, they once again used that
14 definition. In fact, they actually beefed it up a bit to
15 make it more clear that in fact beta-alanine can exist as a
16 component of carnosine. They added the parenthetical (e.g.,
17 carnosine, anserine and balenine) four lines into that
18 definition.

19 So same patent family, they once again made
20 clear that beta-alanine can be included or can exist as a
21 component of a dipeptide or a polypeptide or an
22 oligopeptide.

23 Here are the claims of that very same '084
24 patent in the same patent family. What is claimed? Number
25 9: A dietary supplement comprising a mixture of creatine

1 and anserine or balenine. Well, anserine and balenine are
2 dipeptides. So they haven't disclaimed dipeptides. To take
3 the petition to make special to mean that they disclaimed
4 dipeptides, that can't be the case because neither the
5 examiner, same examiner, nor the applicants, same
6 applicants, treated it as a disclaimer. And that's evident
7 in the prosecution history.

8 This is the final of the related subsequent
9 patent applications. This is the '294 patent that issued,
10 filed in 2002, issued in 2004. This is an actual
11 continuation, a straight continuation. So it has the same
12 specification, including that same definition that I have
13 cited to a number of times.

14 What is claimed in this patent? It is a method
15 of increasing the anaerobic working capacity of a tissue in
16 a subject, similar language that we see in the patents in
17 suit, comprising the following steps. Well, providing a
18 methylated analog of an amino acid selected from a group
19 consisting of carnosine, anserine and balenine.

20 Again, there was no disclaimer of dipeptides.
21 The applicants didn't disclaim it. In fact, they went ahead
22 and claimed it like gangbusters afterwards, and the examiner
23 allowed it.

24 So the examiner didn't understand there was a
25 disclaimer, and the applicants didn't even treat it as a

1 disclaimer.

2 Your Honor, telling is this slide. It is one of
3 the transition slides here. Plaintiffs essentially admit
4 that there is no disclaimer. In their opening brief, they
5 make a very general, very broad statement that the
6 statements by the applicants during the prosecution was a
7 clear and unmistakable disavowal that the applicants'
8 invention encompassed dipeptides such as carnosine that were
9 disclosed and claimed in the Setra reference.

10 They are trying to say there was a disavowal, no
11 claim of dipeptides. Here is what they say in their
12 answering brief down at the bottom. They say, The
13 prosecution history evidences a clear disavowal that any
14 term in the patents in suit encompass dipeptides, such as
15 carnosine or anserine, unless the claim explicitly states
16 dipeptide, anserine, or the like.

17 Recognizing this dilemma that appears due to
18 Claim 3, and recognizing the strength of the definition and
19 the fact that it was reincorporated and the fact that the
20 subsequent prosecution history that we put in our opening
21 brief, they try to have it both ways here, Your Honor.

22 They say there was a disavowal. Well, unless we
23 say there wasn't, you can't do that. Either there was a
24 disavowal or there wasn't. Very clearly -- I won't say very
25 clearly. We believe it is very clear that there was no

1 disavowal.

2 THE COURT: Somebody taught you Appellate
3 Advocacy well when they say don't say "very clearly."

4 MR. DiGIOVANNI: Yes.

5 So I do have some slides on extrinsic evidence.

6 THE COURT: We can skip by these. I was looking
7 at them.

8 MR. DiGIOVANNI: It was only meant to be
9 definitional. I will skip them. We cited them in their
10 briefs.

11 THE COURT: We are going to active derivative.
12 Right?

13 MR. DiGIOVANNI: I have one additional point on
14 beta-alanine and L-histidine. And that is an argument that
15 was made in the brief, in the opening brief and I think the
16 answering brief for plaintiffs.

17 They make their arguments and then they fall
18 back on the argument, well, the Court needs to construe the
19 claim to preserve the validity. We think that maxim, which
20 does have some application but very limited, as Your Honor
21 knows, due to Phillips and other cases, we think it doesn't.
22 In fact, their argument to apply that maxim is faulty, it
23 has four faulty premises. I will go through them, Your
24 Honor.

25 Number one, that maxim is only applied when the

1 claim term is ambiguous. And even then it is still limited
2 even in that context. Your Honor, we would propose or
3 suggest that the claim term is not ambiguous. It is
4 expressly defined in there.

5 To the extent that there is some ambiguity in
6 the prosecution history statements, that doesn't go to the
7 ambiguity of the claims. That goes to whether those
8 statements act as a disclaimer. And that needs to be clear
9 and unmistakable.

10 So you have ambiguous statements at best. Is
11 that a clear and unmistakable disclaimer? No. Then you go
12 to the patent definition, which is very clear. So you never
13 get to the ambiguity that would be required for this maxim.

14 Number two, there are some lesser known Federal
15 Circuit cases. I hesitate to say that --

16 THE COURT: No, it's okay.

17 MR. DiGIOVANNI: -- that say this maxim is also
18 never applied. You can't apply it if the alternative
19 proposed construction is not practicable.

20 So these cases, Generation Two and Rhine, say,
21 the Rhine case says, "The Court has consistently limited the
22 axiom to cases where the construction is practicable."

23 So you need to take a look at the proposed
24 construction and say, well, does it work just as a threshold
25 matter? As we say in Claim 3, their construction doesn't

1 work. It makes an unpracticable claim, Claim 3. So you
2 can't apply this maxim.

3 No. 3, I guess it's a basic principle of the
4 argument that when someone says please construe the claim to
5 preserve the validity as well as the construction ought to
6 actually preserve the validity. In this case it does not,
7 at least Claims 3, 12 and 24. Those are the only claims we
8 identified based on their construction that would be just
9 flat-out nonsensical and inoperative.

10 But I think we can also say that we probably
11 have an enablement problem and an indefiniteness problem if
12 we adopt their construction, which is internally
13 inconsistent with Claims 3, 12 and 24 of the '361 patent.

14 And the fourth of the four faulty premises of
15 their argument that the Court ought to construe the claim to
16 preserve the validity is that the examiner -- they make this
17 argument I think it's at Page 20 of their opening brief,
18 they argue that the examiner recognized that dipeptides were
19 disclaimed by the applicants. I just want to summarize that
20 in fact the examiner did not. He allowed Claims 3, 12 and
21 24, which he would not have allowed if he recognized that in
22 fact dipeptides were disclaimed. The applicant in the
23 Patent Office allowed carnosine claims in the '294 patent,
24 which is a subsequent patent in the family, and he allowed
25 anserine and balenine claims, also dipeptides claims, in the

1 '084 patent.

2 So the argument made by plaintiffs that the
3 examiner recognized that dipeptides were disclaimed is just
4 faulty.

5 Your Honor, my next slides deal with active
6 derivative. So I am going to switch gears just a little bit
7 here.

8 THE COURT: Okay.

9 MR. DiGIOVANNI: I have separate slides for
10 active derivative, Your Honor. But I will keep my
11 definition up on the easel.

12 THE COURT: I have it in front of me as well.

13 MR. DiGIOVANNI: That is fine. I don't have an
14 easel definition of active derivative. So that's great.
15 Terrific.

16 So just taking a look at the parties' dueling
17 proposals, they are identical up to a point. So both
18 parties agree that the first part of the definition should
19 apply. That is, compounds derived from or a precursor of
20 the substance that performs in the same or similar way in
21 the body as the substance or which is processed into the
22 substance and placed into the body.

23 The difference between the two, and I
24 highlighted it in red in this slide, in the right side,
25 plaintiffs add a kicker at the end. They say, okay, they

1 ask the Court to add something at the end of that definition
2 that excludes dipeptides, oligopeptides and polypeptides.

3 So I am going to skip this, Your Honor. I think
4 that was covered.

5 Where are both parties getting their definition
6 from? Well, they are both getting it from the definition
7 that the applicants, the inventors, set forth in their
8 patent. Defendants' proposed construction is verbatim, word
9 for word, the definition that was set forth by the
10 inventors. It's a clear, unambiguous definition. So it's a
11 specific definition that is adopted verbatim by the
12 defendants.

13 Now the case law says the patentee's definition
14 controls. So where do the plaintiffs get this kicker from?
15 I call it a validity kicker because their argument for it at
16 their opening brief at 16 essentially is stating, okay,
17 there is a definition, they acknowledge there is a
18 definition in the patent, but they say -- and it's the
19 lowest of these four yellow highlights -- but they say,
20 well, certain things do not fit within the meaning of the
21 active derivative that is set forth in the patent in suit.
22 Therefore, they want to include that in the definition.

23 Well, Your Honor, I would say that that is not
24 the role of claim construction. The claim construction is
25 to determine the -- this is from their brief, this is their

1 own words -- claim construction is, of course, to determine
2 the meaning of active derivative. Whether something fits
3 within the meaning of it, that's not claim construction.
4 That is something that needs to be determined by the
5 fact-finder, either at summary judgment or trial or
6 otherwise.

7 But that is not claim construction. Claim
8 construction is figuring out the meaning of a term.

9 That is what defendants have done. The meaning
10 is expressly stated by the inventors.

11 Another important point here, Your Honor, is
12 that the term -- this is what I was alluding to earlier when
13 I advocated for the active derivative to be addressed
14 separately. That is, the term active derivative never
15 appeared in the claims until the '361 patent. And Mr.
16 Chambers acknowledged that.

17 That is why we didn't want to get that tied up
18 with this prosecution argument that was made in the earlier
19 patent, because the claim term active derivative never
20 appeared in the claims until the '361 patent. And the
21 Federal Circuit case law says the doctrine of disclaimer
22 doesn't apply when the claim term in the descendant patent
23 uses different language.

24 I just wanted to make that emphasis.

25 Your Honor, with that, that's what I have on

1 those terms.

2 THE COURT: Thank you, Mr. DiGiovanni.

3 MR. HANSEN: Your Honor, may I supplement a
4 couple points on behalf of DNP?

5 THE COURT: Yes. Mr. Hansen.

6 MR. HANSEN: Thank you, Your Honor.

7 I want to address a couple of points from the
8 plaintiffs' presentation specifically.

9 One point that was made a couple of times is
10 that, well, once you have the dipeptide you no longer have
11 the amino acid. What you have are amino acid residues, and
12 those aren't the same things as the amino acids. And that
13 is actually scientific incorrect, is what I believe they
14 said, to call the components of the dipeptide amino acids
15 because they are in fact residues.

16 That may be all well and good. But the truth is
17 it's the inventors who said that. If it is scientifically
18 incorrect, it's based on what the inventors said.

19 Here on Slide 42 we have the portion of the
20 specification, not the highlighted portion, but above it, it
21 says, "Each of the beta-alanine or L-histidine can be
22 components of dipeptides."

23 What it doesn't say is that beta-alanine
24 residues and L-histidine residues can be components of
25 dipeptides.

1 What we are really talking about here in the
2 claim construction language is how is the language used.
3 The way the inventors used this language is to describe
4 beta-alanine and L-histidine as components, not residues
5 thereof. That is really what we are here about today, is to
6 figure out how those terms were used and what they mean.

7 One thing I think we should do also is step back
8 for a moment. We are in a slightly different situation here
9 where the patent holder is saying, well, we described what
10 the invention meant in our petition to make special. And
11 it's somewhat odd because the patent holder was in the
12 unique position to draft patent claims to explain exactly
13 what they meant.

14 So it's a little odd to take one document filed
15 in the late 1990s out of this whole series of patents and
16 say that it now describes what the scope of the claims is.
17 I think that's something to keep in mind as the Court
18 considers the parties' positions.

19 One other point I wanted to make. Plaintiffs'
20 counsel talked about the analogy of an apple and that the
21 apples lose their identity. Not really applicable here, for
22 reasons that are actually stated in the patent. I want to
23 show an excerpt from the '361 patent.

24 If we look here in Column 5, if we go down to
25 Line 12, actually let's look at Line 11, the

1 beta-alanyl-L-histamine dipeptides --

2 THE COURT: Would you blow that up a little bit.

3 The first paragraph there, Line 11.

4 MR. HANSEN: The beta-alanyl histimine dipeptide
5 is synthesized within the body from beta-alanine and
6 L-histidine. These precursors can be generated within the
7 body or are made available by the diet, including from the
8 breakdown of an ingested beta-alanyl-histidine dipeptide.
9 That beta-alanyl-histidine dipeptide is carnosine, as we
10 described in the tutorial.

11 Actually, in this case if you eat the apple pie
12 you get the apples back in the bloodstream. So the apple
13 pie analogy is not really applicable here, as their own
14 teachings indicate. I wanted to point that out.

15 One final point then, Your Honor. The Court
16 raised the issue of the Genentech case and whether there is
17 multiple definitions. We want to make clear that our
18 position is there are not multiple definitions.

19 THE COURT: I think that's why you
20 distinguished --

21 MR. HANSEN: Exactly. Our position is it is a
22 single definition which describes multiple forms in which --

23 THE COURT: I was being inartful in my questions
24 to Mr. DiGiovanni. I do understand him on that.

25 MR. HANSEN: I wanted to clarify that point.

1 Thank you, Your Honor.

2 THE COURT: Mr. Chambers.

3 MR. CHAMBERS: Your Honor, I am afraid we are
4 going to have to re-plow a little bit of ground because I
5 consider later applications in the same family to be
6 extrinsic evidence, and I didn't cover some of the other
7 areas where they dealt with that.

8 The reason for that --

9 THE COURT: Let's make clear your position,
10 because I thought when I was first discussing the whole
11 notion of extrinsic evidence, I thought it was the
12 plaintiffs' position that if the patents were from the same
13 family you didn't consider it to be extrinsic. When you
14 stood up to object and when that was pointed out by Mr.
15 DiGiovanni that it was from the same family you didn't
16 pursue the objection.

17 MR. CHAMBERS: Your Honor, exactly. I had
18 thought that what we were saying was that something that
19 came after the patent issued was extrinsic. And that's why
20 I didn't put this into my stuff. That's why I was going to
21 object. But then after he raised it and you made the point
22 that, well, if it is from the same family we will let it in,
23 I thought that there wasn't an issue. Part of the reason
24 for this is that defendants in their brief indicated that
25 there was a particular application that became a patent.

1 And they said it was in the same family. It's not in the
2 same family. And we were ready to show that it wasn't in
3 the same family.

4 But that's not the application and the patent
5 that they spoke about. That was a different one. You can
6 find it in the brief and we can show why, even though it's
7 on the front of the patent claiming to be in the same
8 family, the prosecution history of that patent makes it
9 clear --

10 THE COURT: But that's not this patent that --

11 MR. CHAMBERS: Exactly. I will re-plow a little
12 ground. First I want to cover that Claim 3 that was in the
13 '361 patent.

14 Claim 3 in the '361 is unusual because it
15 doesn't say the way we often talk in patent law.

16 Usually in patent law, we will say something
17 like it comprises, the invention comprises, or that the
18 invention -- I will have to switch over. Let's just look at
19 this particular Claim 1 here. We will blow it up.

20 The composition comprising a mixture of creatine
21 composition comprising an amino acid, an active derivative
22 of the beta-alanine, an ester of beta-alanine or amide of
23 beta-alanine, that is Claim 1. That claim itself can issue.
24 That claim was determined to be something that was
25 patentable.

1 THE COURT: It's an independent claim. Right?

2 MR. CHAMBERS: Exactly. So if you add an
3 additional limitation to a dependent claim, you can get that
4 allowed. There was a suggestion or a statement that, well,
5 they say here that they disclaimed dipeptides, but you find
6 it in Claim 3. It's true you find it in Claim 3. You gain
7 the ability to get the patent in Claim 1, and then you add
8 something further. In this particular claim construction,
9 in this particular claim, it doesn't say something that the
10 composition of Claim 1 wherein beta-alanine is a dipeptide.
11 It says where a composition further comprises, has addition
12 to it. If you look at their particular --

13 THE COURT: I get that point.

14 MR. CHAMBERS: Okay. When they substituted
15 in -- well, it's really saying that in addition to the
16 beta-alanine you have this dipeptide.

17 THE COURT: It's a term of art. I understand it
18 well.

19 MR. CHAMBERS: You also see that same
20 construction there for Claim 2 further comprises
21 L-histidine. So it has something extra.

22 But look at Claim 4. It says the composition
23 where the creatine is creatine monohydrate.

24 So they knew how to make that narrowing
25 definition that you commonly find in patent law that leads

1 to claim differentiation. This isn't claim differentiation
2 in the same way. This is saying that for the first claim
3 you claim the beta-alanine and then anything you want to put
4 in beta-alanine is still in that big genus.

5 For Claim 3 not only do you have to have
6 beta-alanine, but you have got to also in addition to
7 beta-alanine have to have a dipeptide and oligopeptide or
8 polypeptide. On Page 44 of their presentation --

9 THE COURT: The citation to Phillips?

10 MR. CHAMBERS: -- where they substituted in the
11 meaning of the term.

12 THE COURT: I am not sure where that is.

13 MR. CHAMBERS: I thought it was Page 44 of their
14 prosecution --

15 THE COURT: You mean their slides?

16 MR. CHAMBERS: In any event, Your Honor, the
17 examiner did not know did not misunderstand what a dipeptide
18 was. The examiner knew exactly what a dipeptide was. It
19 was saying that this was the dipeptide. Then further you
20 had beta-alanine, but it was something in addition.

21 I am sorry, it was Page 17.

22 Here it says, The composition of Claim 1 wherein
23 the individual amino acid beta-alanine or its salt ester or
24 amide further comprises a dipeptide. All that is saying is
25 that that particular composition further includes or has to

1 have in addition a dipeptide, an oligopeptide, or a
2 polypeptide. That is all that that means.

3 Now, they suggested that the disavowal is for
4 all of the subject matter forever. And our position is that
5 when you disavow something, you are disavowing the claim
6 terms. You can go back and you can actually claim material
7 that was another embodiment in the patent when you filed it.
8 This patent has many embodiments. Some of those embodiments
9 were dipeptides. And later patents actually claim those
10 dipeptides.

11 But we are talking about what the claims in the
12 patent in suit mean, not whether or not they have disclaimed
13 something so that they can never resurrect it in a
14 subsequent patent.

15 THE COURT: I am just curious. We don't get to
16 make policy. What do -- I will get both of you up here --
17 what do you imagine the Federal Circuit and the Supreme
18 Court, more importantly, perhaps the United States Congress,
19 the framers of the Constitution intend patents, what is
20 their option? It is to perform a public notice function --
21 right -- to those of skill in the art as to what the metes
22 and bounds of a particular property claim are. Right?

23 So in analyzing that -- and Vitronics picks up
24 on this and many other cases, Phillips certainly re-embodies
25 and does not in any way diminish Vitronics, says to us

1 that -- and this has to do with extrinsic evidence,
2 understanding that the prosecution history is part of the
3 intrinsic record. Nonetheless, what do people skill of
4 skill in the art typically do? Don't they read the claims
5 and the written description to try to understand where the
6 parameters are?

7 How involved in the prosecution history, in
8 analyzing the prosecution history, things like disclaimer,
9 prosecution history estoppel, must one of skill in the art
10 get in order to determine whether he or she can avoid the
11 patent or design around or things that are appropriate to
12 do?

13 MR. CHAMBERS: I think that the claims put
14 someone on notice. As we all know from looking at opinions
15 of counsel for freedom to operate opinions and things like
16 that, the Federal Circuit has said that a freedom to operate
17 opinion that does not include an investigation of the
18 prosecution history is incompetent. And so what they are
19 saying is, hey, the claims put you on notice. And then it's
20 not like they said in years past that you should burn the
21 file wrapper so that you only have those claims. You look
22 at the claims, the specification, and then you ask, do I
23 still have an issue? And if you do, then you are going to
24 want to say, okay, I better have a trained professional look
25 at this because otherwise, there might be an issue.

1 So I think, you know, Congress put this out.
2 And, yes, they want to advance science and the useful arts
3 and they want to encourage patents. But they know that
4 sometimes scientists don't always speak with the same
5 language that is the vernacular for everyone else. So if
6 you can get it from the specification, that is fine. But if
7 there is any doubt, you better go to the prosecution
8 history.

9 THE COURT: I certainly agree with you on that.
10 How could I not? But I worry a little bit for skilled
11 artisans insofar as -- sure, go out and get a competent
12 legal opinion. Get a good outfit to sit down. But even the
13 best may not be able to anticipate the intricacies, the
14 creativity of good advocates like yourself who come later on
15 and say, We disclaimed.

16 It just seems to me to be a really slippery
17 slope.

18 That is a discussion perhaps for a class of mine
19 or another day.

20 Go ahead.

21 MR. CHAMBERS: Your Honor, I guess the issue
22 really is, given what was said in that JA73 and 74, where
23 they said that the beta-alanine and the L-histidine were
24 mono peptides, they said that twice and then they distinguish
25 it over the dipeptides, I don't see how for that particular

1 claim there can be any doubt that they were disclaiming it.

2 Now let's look at Slide 18, Mr. McKeague, and
3 also your Exhibits B and C.

4 In patent law we all know you can't get a second
5 patent if you have already gotten a patent for the first
6 thing, unless you file a terminal disclaimer. It's called
7 double patenting. In a later filed application, not one of
8 the patents in suit but within the same family, it was a
9 CIP, and it's the one we have been speaking about, in those
10 particular later filed applications, it's not, as the
11 defendants said, that this issue wasn't raised more than
12 once. This issue came up. But the issue came up in a way
13 that makes it pretty clear, that makes it absolutely clear
14 that they were disclaiming the dipeptides.

15 Now, in that later filed application, the patent
16 examiner said that the patents in suit and that the claims
17 of these patents in suit compared to the CIP were either,
18 one, obvious variants, or if they weren't obvious variants
19 they were something that still had to be practiced in order
20 to perform the CIP claims because the CIP would be required
21 to do them but it would allow additional materials to be
22 added.

23 How do I get rid of this little red mark that is
24 on here, Your Honor?

25 THE COURT: That is your presentation. I don't

1 know.

2 MR. MOORE: There may be a way to clear the
3 screen.

4 MR. CHAMBERS: We can talk around it.

5 The examiner said in the patent prosecution that
6 we are talking about here, said that the claims were either
7 obvious variants of the patents in suit or you couldn't
8 practice the claims of this CIP without practicing the
9 patents in suit because in those particular patents in suit
10 it allowed additional nonspecific additions.

11 Let's look what it says. He rejects it. Then
12 we have got these three patents up here are the patents in
13 suit. They are not patentably distinct from each other
14 because either one set of claims is obvious over the
15 variants of the other claim sets or a skilled artisan would
16 not be able to practice the invention of the claims set
17 without practicing the invention of the other claim sets in
18 particular because the transition phrase "comprising" --

19 THE COURT: Can't see it.

20 MR. CHAMBERS: Thank you. -- "comprising
21 employed in the claim sets which allows additional
22 non-specified elements covering the claim."

23 Now, that means two very important things, Your
24 Honor. The first is that the examiner did not see these
25 claim sets as ADOP. He didn't see them as amino acid,

1 dipeptide, polypeptide or oligopeptide. Otherwise, they
2 wouldn't be obvious variants. But they would be covering
3 the same subject matter. In other words, you would have an
4 "I claim this in one and I claim that in the other one."

5 And there is a second thing that's taught.
6 These earlier claims did not claim the dipeptides because
7 they only rendered the claim obvious due to additional
8 nonspecific additions.

9 In other words, it wasn't that beta-alanine
10 included ADOP. It was beta-alanine. It was a comprising
11 claim. So it was open-ended. That's what made the examiner
12 say, wait a minute. This is not acceptable. In other
13 words, if ADOP were correct, the dipeptide would not be what
14 the examiner called additional nonspecific additions because
15 of the comprising, but would already be something that was
16 there in the claims.

17 Then the applicants filed their response. And
18 for each one of the patents the applicants went through and
19 they said none of the methods of Claims 1 through 11 of the
20 '596 patent recite or encompass a composition that contains
21 a mixture of creatine, anserine or balenine. Those are the
22 dipeptides. So none of those contain that. That is for the
23 '596.

24 For the '098, they say neither Claim 3 nor Claim
25 4 of the '098 patent recites a composition that includes a

1 mixture of creatine, anserine or balenine.

2 And for the '361 patent, they say that none of
3 the claims recite a dietary supplement that includes a
4 mixture of creatine and the dipeptides. So once again they
5 were disclaiming the dipeptides.

6 Now, if you look at that response, they indicate
7 that dipeptides are not encompassed by the earlier patents
8 no less than ten times. You can find that, that is the
9 McKeague declaration, Exhibit C.

10 So we think that it was clear the first time
11 when Setra said -- when they said Setra teaches dipeptides,
12 if it meant ADOP, it's 102 anticipation. You can't issue
13 that. We think the examiner knew what he was doing. He was
14 just being very precise in analyzing what was there.

15 Now, there seems to be some issues regarding
16 Genentech. The Court has indicated an interest in
17 Genentech.

18 THE COURT: Only because the parties cite it.

19 MR. CHAMBERS: We believe Genentech would apply
20 if you consider there to be multiple definitions. We think
21 that the disclaimer is pretty clear. We think that --

22 THE COURT: Do you consider there to be multiple
23 definitions? Do you agree with the defendants that there
24 are not multiple definitions?

25 MR. CHAMBERS: Your Honor, what we believe is

1 there aren't multiple definitions, it is clear. But even if
2 there are, Genentech says it should go a certain way.

3 THE COURT: Genentech, the Court there was
4 dealing with multiple definitions. And they made it clear
5 that that is what they were dealing with. If you are in
6 agreement, I don't have to re-read Genentech again. It's
7 not an issue.

8 MR. CHAMBERS: Your Honor, they say that
9 Genentech went down to structural issues. We believe that
10 these are structural issues, too. The definition of
11 beta-alanine just like in Genentech --

12 THE COURT: That is what the Court did in order
13 to discern the meaning of the terms at issue. The principal
14 issue, it seems, is there is no disagreement between the
15 parties or at least the present situation is --

16 MR. CHAMBERS: Your Honor, we don't
17 believe there are multiple definitions.

18 THE COURT: Counsel, don't interrupt. I am
19 going to interrupt you from time to time, but that's what
20 judges do.

21 Tell me if you disagree. It sounds to me like
22 there is agreement among the parties that Genentech really
23 doesn't apply in this case because there are not multiple
24 definitions. Yes or no?

25 MR. CHAMBERS: I agree, Your Honor.

1 THE COURT: We don't need to talk about
2 Genentech anymore.

3 MR. CHAMBERS: We believe, Your Honor, there is
4 one definition -- when you file an application --

5 THE COURT: Go back to the podium, counsel,
6 unless you need to use the Elmo.

7 MR. CHAMBERS: I have just blanked. I should
8 have stayed up there at the Elmo.

9 THE COURT: Go back. It may jog your memory
10 somehow.

11 I know the feeling. Take your time. You were
12 talking approximately Genentech and...

13 MR. CHAMBERS: I am sorry, Your Honor.

14 When you file an application at the Patent
15 Office, you file it, and then many months later it gets
16 acted on even if you file a petition to make special. You
17 have crafted a particular application, you file it, and then
18 during prosecution you will narrow the claim, you will
19 narrow what you are going after. And that's why prosecution
20 history is very important in finding out what the applicant
21 eventually intended or eventually obtained.

22 THE COURT: Counsel, I understand prosecution
23 history. I really do.

24 MR. CHAMBERS: Counselor has indicated that
25 Phillips doesn't say -- or says that the lexicography

1 governs. Phillips is very clear about the prosecution
2 history, the importance of the prosecution history.

3 THE COURT: Wait a minute. Phillips doesn't say
4 anything different that hadn't already been said previously
5 regarding lexicography. Do you disagree with Mr.
6 DiGiovanni's statement of the legal proposition?

7 MR. CHAMBERS: If his statement of the legal
8 proposition is if you have some ambiguous definition in this
9 the specification --

10 THE COURT: That is not what he is saying. I
11 don't understand him to advance the proposition that you
12 only go to the concept of lexicography if there is
13 ambiguity. What I believe the cases say is that the
14 applicant is free to act as his or her own lexicographer.

15 Is that your contention, Mr. DiGiovanni?

16 MR. DiGIOVANNI: It is, Your Honor.

17 THE COURT: Do you agree with that?

18 MR. CHAMBERS: Absolutely Your Honor. Then the
19 applicant is also free to narrow that definition.

20 THE COURT: Yes, certainly, in the
21 back-and-forth, in the negotiation that occurs between the
22 examiner and the applicant, that happens. We know that.
23 Okay.

24 MR. CHAMBERS: Your Honor, I may have misspoke.
25 Originally, when I said Genentech doesn't apply, there is

1 another way to look at this. And if you are saying that
2 there are multiple definitions and that the one is a
3 definition of an amino acid and the second definition is a
4 component of a dipeptide and the third is a definition of
5 how the active derivative plays in with that, then there
6 would be multiple definitions. I don't believe that, the
7 way I look at it, that they gave a definition of
8 beta-alanine that included the residues in those dipeptides
9 in terms of the claims of the patents in suit.

10 THE COURT: Who is "they"?

11 MR. CHAMBERS: The inventors.

12 THE COURT: But I was only trying to understand
13 your position for purposes of this exercise as to whether
14 there are multiple definitions. And that was the context of
15 Genentech, I thought. I thought you said, No, there are not
16 multiple definitions being advanced by the plaintiff. Is
17 that your position?

18 MR. CHAMBERS: That's correct, Your Honor. But
19 if the Court construes it as there is a definition that it
20 is an amino acid and a definition that it is the residue of
21 a dipeptide, then, under that consideration or under that
22 analysis, I would say, okay, yeah --

23 THE COURT: I will make it clear in a footnote
24 or two in my order as to whether I am applying Genentech. I
25 will try to do that. I don't think I am going to have to go

1 there. But go ahead.

2 MR. CHAMBERS: Finally, Your Honor, the claims
3 that were spoken of by the defendants dealing with the '294
4 patent, those are claims that don't even use the term
5 beta-alanine and don't even use the term L-histidine. Those
6 are claims that don't go there. So I don't see how they
7 help to illuminate what beta-alanine means or L-histidine
8 means. Instead, those claims address dipeptides and
9 indicate very clearly what's being claimed.

10 With that --

11 THE COURT: Here is what I am going to do. We
12 can't spend as much time on other terms. But my sense is
13 that this is, as it were, sort of where the rubber meets the
14 road in this case, these three terms we have been talking
15 about. So I am going to do something I don't typically do.
16 I am going to let Mr. DiGiovanni respond. And then I will
17 give you the last word.

18 MR. DiGIOVANNI: I appreciate that, Your Honor.
19 Thank you very much.

20 I will start by addressing your question about
21 the public notice function and Congress and the Supreme
22 Court.

23 I certainly agree that the public notice
24 function is of critical importance. I think Congress is
25 currently debating this American Events Act and looking to

1 protect American companies and other companies around the
2 world when it comes to inventing and having a good
3 understanding of what is already patented and how to avoid
4 patents, et cetera. So the public notice function is
5 critical. That is why the Federal Circuit has stated that
6 when you have a prosecution history statement, it needs to
7 be clear and unmistakable. I think Mr. Chambers on several
8 occasions said, I think it's pretty clear that... That
9 doesn't cut it. Even if it were pretty clear, we certainly
10 don't agree that there was anything even close to pretty
11 clear or clear or even a disclaimer.

12 There just was no disclaimer that was clear and
13 unmistakable that a person of ordinary skill in the art in
14 reviewing the entire file, the patents, and the prosecution
15 history would understand that, in fact, these particular
16 inventions that were covered by the express definition were
17 excluded. An inventor wouldn't do that, especially in view
18 of Claim 3, Your Honor.

19 I want to go back to Claim 3. Let me just make
20 a switch here.

21 We have up on my Slide 36. Going back to this
22 Claim 3 situation, this slide, while it doesn't show Claim
23 1, Claim 1 talks about a composition that further comprises,
24 and goes on and describes it. Claim 3 doesn't say where the
25 composition further comprises a dipeptide. Claim 3 says,

1 wherein the beta-alanine further comprises a dipeptide,
2 oligopeptide, or polypeptide.

3 There is no way to read that without coming to
4 the conclusion that, well, that means a beta-alanine. As
5 that term is used by the inventors, there is no way to read
6 that without understanding that beta-alanine does, in fact,
7 encompass beta-alanine as a component of the dipeptide and
8 oligopeptide and polypeptide.

9 I think what plaintiffs argued was -- and I am
10 not completely sure this is what they argued -- but
11 apparently they are saying you have a beta-alanine, and then
12 you have something else attached to it, then you have
13 something else. And they say, well, that would still be the
14 beta-alanine individual molecule. No, it certainly
15 wouldn't. Their definition would expressly preclude the
16 beta-alanine from being called beta-alanine because their
17 beta-alanine says it has to be by itself.

18 Once you have beta-alanine further comprising a
19 dipeptide, once it's part of that bigger chain, then under
20 their definition it is no longer beta-alanine. Well, that
21 is completely inconsistent with Claim 3.

22 So going back to the public notice function and
23 the rules of claim construction, there is a requirement that
24 all the claims need to make sense. And their construction
25 completely destroys that.

1 Just a couple other points.

2 The CIP application, Your Honor, I think they
3 are arguing for an after-the-fact reverse disclaimer. In
4 these earlier patents, you can't do that. I don't
5 understand their later arguments to have any effect on claim
6 construction.

7 And the arguments had nothing to do with the
8 definition of beta-alanine that a person of ordinary skill
9 in the art would understand in reading their patent, where
10 there is an express definition and reading the claims and
11 the prosecution history.

12 And then I don't need to address Genentech, Your
13 Honor, because there is one definition, and the definition
14 is up on the poster board, because we adopt ours directly
15 from the inventors' definition, and I just don't see how
16 that can be multiple definitions.

17 I think that's all I have, Your Honor.

18 THE COURT: All right. We will give Mr.
19 Chambers the last word on this round.

20 MR. CHAMBERS: Your Honor, just two minor
21 points. I am sorry for my Midwestern upbringing that makes
22 me say "pretty clear" rather than "clear." I think it's
23 quite clear.

24 But in addition --

25 THE COURT: Is that a unique feature to

1 Midwesterners?

2 MR. McKEAGUE: It is, Your Honor.

3 THE COURT: We have got some affirmation here.

4 MR. McKEAGUE: It is.

5 MR. OPARIL: It is extrinsic evidence, Your
6 Honor.

7 (Laughter.)

8 MR. CHAMBERS: Your Honor, when they say that
9 the beta-alanine further comprises a dipeptide, the other
10 way to look at that is that the beta-alanine is a dipeptide
11 of beta-alanine and it's not the carnosine dipeptide, in
12 other words, that it can be two beta-alanines linked
13 together. So we don't see that this precludes having Claim
14 1 address just that it's just the amino acid.

15 In addition, one of the things that I had needed
16 to address earlier was that when they had indicated that the
17 present invention provides for dipeptides, peptides, and
18 peptide analogs, as explained in our brief, Your Honor, that
19 is referring to the invention and what goes on in the
20 muscles and what goes on in the cells. That is not saying,
21 you know, that this is addressing the particular way that
22 you interpret the claims.

23 THE COURT: All right. Why don't we take a
24 bio-break and come back in a few minutes.

25 (Recess taken.)

1 THE COURT: Please take your seats.

2 I am hoping we can get through the rest of this
3 by 1:00. That would be my preference, quite frankly.

4 MR. CHAMBERS: I believe we can.

5 THE COURT: All right.

6 MR. CHAMBERS: The next term that we are going
7 to consider, Your Honor, is dietary supplement.

8 We believe dietary supplement means in addition
9 to the normal diet, in the form of a pill or capsule,
10 tablet, a powder or a liquid form, which is not a
11 conventional food and effectively increases the function of
12 tissues.

13 Now, dietary supplement must be construed. If
14 you look at the --

15 THE COURT: There is a disagreement among the
16 parties over that. Right?

17 MR. CHAMBERS: Yes. The defendants have
18 indicated that it shouldn't be construed because --

19 THE COURT: It's in the preamble.

20 MR. CHAMBERS: -- it's in the preamble.

21 However, looking at the actual patent, you find
22 that Claim 1 and Claim 5 are exactly the same except for the
23 term dietary supplement and composition. I have highlighted
24 those for Claim 1 and Claim 5.

25 You find that same issue for Claim 10 and Claim

17: composition and dietary supplement.

Finally, in 22 and 25, it simply says dietary supplement. That is the only change in those terms.

If dietary supplement did not have meaning, the Patent Office would have been issuing not only two claims to exactly the same thing, exactly the same invention, but three sets of claims to exactly the same invention. They would have done this three times. We don't believe that that is the case.

In addition, we believe that dietary supplement is very important for the claim term.

The second and third paragraphs of the patents in suit describe dietary supplements. These are typically not conventional food. Specifically, the patents in suit disclose the importance of supplements to compensate for the reduced levels of nutrients in the diet. For example, at Exhibit 3, Joint Exhibit 3, Column 1, Lines 18 through 21, that demonstrates that the applications are intended that the supplements of the invention are something other than simply conventional food because they were intended to compensate for reduced levels in the diet.

In addition, conventional foods like meat and animal products can't be used as a supplement to diets of certain people like vegetarians, it is something that the patent is not saying to use conventional foods to alleviate

1 these issues, but to use a dietary supplement.

2 For example, in Exhibit 3, Column 3, Lines 54
3 through 59, it says that you lose some of these with
4 conventional cooking. Beta-alanine only comes from animals.
5 So you wouldn't be getting it if you were a vegetarian.
6 It's got to come from a dietary supplement, something that
7 is not conventional food.

8 Now, when referring to natural foods, the
9 patents don't call them dietary supplements. For example,
10 at JX-3, Column 11, Line 56, it refers to chicken broth as a
11 natural food, not as a dietary supplement. These substances
12 are not food themselves.

13 In addition, when they are adding the
14 beta-alanine amino acid to feed, they say that these
15 substances were added to the feed. And if they were
16 actually feed themselves it wouldn't be stated that way.

17 If you went to a pharmacy, Your Honor, and asked
18 for a dietary supplement, and the pharmacist said you can
19 get chicken breasts over in Aisle 4 and broccoli over in
20 Aisle 3, you would think he misunderstood you. That is not
21 the way people normally use the terms. This is something
22 that needs to be construed because the Patent Office doesn't
23 issue multiple claims for the same invention.

24 We will hear from the defendants now?

25 MR. HANSEN: Your Honor, we have on the screen

1 Slide 48. What we have done here is on the left-hand side
2 we have shown defendants' construction, on the right-hand
3 side, plaintiffs' construction. And then what we have done
4 on each side is explaining the parties' positions.

5 As plaintiffs' counsel pointed out, there is two
6 key issues here. The first is do we even get to the
7 construction issue. We contend that we do not, because
8 dietary supplement is not a limitation.

9 The second issue is if the Court decides it has
10 to construe the term, how should it construe it. As shown
11 here on Slide 48, we contend that dietary supplement is a
12 mere statement of intended use and it should not be
13 construed by the Court. And there are several reasons for
14 that. They are summarized here on the right, and we will go
15 through them individually.

16 First, it's recited only in the preamble, and
17 the bodies of the claims do not refer back to the term.

18 Second, the phrase dietary supplement was not
19 used to distinguish the prior art in the prosecution of the
20 '361 patent, which is the patent in which the term appears.

21 And finally, the specification does not
22 demonstrate that the term dietary supplement is a necessary
23 and defining aspect of the invention. It merely says that
24 the composition can be a dietary supplement.

25 When we are looking at the specification, we

1 have to take a look at whether we have words that are
2 mandatory or requirements versus just words that describe
3 possible embodiments.

4 We have reprinted the claims from the '361
5 patent here just to illustrate with the yellow highlighting
6 that dietary supplement does indeed occur only in the
7 preamble. This term "comprising" is known as a transition
8 word in patent claim drafting, and dietary supplement occurs
9 in the preamble, and there is no subsequent reference made
10 to it after the word comprising. That doesn't seem to be in
11 dispute.

12 The phrase dietary supplement was not used to
13 distinguish the prior art in the prosecution of the '361
14 patent. Now, the Federal Circuit has certain recognized
15 circumstances under which a preamble may be limiting. One
16 of them is if the preamble is subsequently referred to in
17 the body of the claim. As we just explained, that is not
18 true here. One of the other ones is if the preamble is used
19 to distinguish the prior art. And again, that wasn't the
20 case here. And so, not surprisingly, we didn't see anything
21 from the plaintiffs showing that there was any mention made
22 of it.

23 So the plaintiffs in their briefing seem to
24 hinge their argument on the fact that the dietary supplement
25 phrase is a necessary and defining aspect of the invention.

1 We have excerpted the quote from the brief here on Page 13
2 of the opening brief. Really, the specification doesn't say
3 that.

4 What we have done on Slide 51 is we have
5 excerpted places in the specification that refer to the term
6 dietary supplement. Column 3, Line 40, The composition can
7 be a dietary supplement. At Column 5, Line 55, The
8 composition can be ingested as a dietary supplement.

9 These are not words of exclusion or requirement,
10 the type of words that the Federal Circuit typically looks
11 to when they are saying that the claims should be limited to
12 something in the specification. And it doesn't indicate
13 that the use of this as a dietary supplement is a necessary
14 or defining aspect of the invention, despite the plaintiffs'
15 suggestion otherwise.

16 Now, I want to address one of the points that
17 plaintiffs' counsel made initially, which is that if this
18 term is not construed that it would render certain claims
19 identical to one another.

20 And just to refresh the Court's recollection,
21 counsel showed the claims of the '361 patent, and there is
22 actually sets that say composition and dietary supplement,
23 and those sets have the same limitations in the body of the
24 claims.

25 And what counsel said is, well, if you accept

1 defendants' contention that the preamble not be construed,
2 these pairs of claims would be rendered identical. We don't
3 disagree. The bodies of the claims are the same. So if the
4 preambles are not limitations, they would be the same. The
5 question is what is the import of that.

6 Now, plaintiffs' counsel also said the Patent
7 Office doesn't issue patents with the same claims in them.
8 There is a rule in the Patent Office that you are not
9 supposed to issue the same claim twice in the same patent.

10 But it's a Patent Office rule. The Court would
11 not be rendering the claims invalid by failing to construe
12 the preamble. It would merely be saying that in this
13 instance the Patent Office rule was not adhered to.

14 Now, the Federal Circuit has laid out the
15 circumstances under which we are to treat a preamble as a
16 limitation. And as we said, it's when it's referred back to
17 in the body or when it's described as a defining and
18 necessary aspect of the invention or when it's used in the
19 file history.

20 In our view, this consideration that some claims
21 might be rendered duplicative simply doesn't trump those
22 Federal Circuit principles. If it turns out that the claims
23 are duplicative, well, then, the examiner should have
24 handled it differently and required them to put something in
25 the body of the claim to make the thing actually a dietary

1 supplement.

2 THE COURT: Is it always the case -- maybe this
3 isn't exactly that. I am trying to remember the Federal
4 Circuit precedent that says when a Court is presented with a
5 dispute it must resolve the disputed definition of claim
6 terms. This isn't exactly that situation, is it?

7 MR. HANSEN: I don't think the Court needs to
8 resolve the construction dispute if as a threshold matter it
9 finds the preambles are not limiting.

10 THE COURT: If I don't find that threshold, I
11 would to resolve that.

12 MR. HANSEN: Then I believe if there is an
13 actual dispute, it would have to be resolved.

14 THE COURT: All right.

15 What would be wrong with, if I did determine
16 that it needed to be resolved, that there was a dispute ,
17 the plain and ordinary meaning of dietary supplement?

18 MR. HANSEN: Well, then, the fact-finder is
19 going to look at individual pieces of prior art and
20 conclude, make some determination as to whether the thing is
21 a dietary supplement as opposed to something that just has
22 what's in the body of the claim. I don't know what that --
23 I don't know how they are going to make that determination
24 if it was just left unconstrued.

25 THE COURT: Well, the construction would be its

1 plain and ordinary meaning.

2 MR. HANSEN: The problem is that that plain and
3 ordinary meaning would further limit the claim, and the
4 fact-finder might say that certain pieces of prior art are
5 not invalidating because they have applied that plain and
6 ordinary meaning.

7 The thing I just wanted to emphasize here is
8 that plaintiffs' argument about the import of this rendering
9 certain claims redundant is somewhat inconsistent with their
10 other position. How can it be the case that dietary
11 supplement is a necessary and defining aspect of the
12 invention if in the same patent they included claims that
13 just say a composition?

14 This seems to be the principle that they are
15 relying on in the first instance to warrant limiting the
16 claims to the preamble. And yet the fact that they recite
17 composition claims which don't even use the words dietary
18 supplement seems to undercut that position.

19 So if the Court is inclined to construe the
20 term, then the question is, how should it? And that's what
21 we are going to look at in the next set of slides.

22 Okay. Here again we have repeated the
23 construction, so we contend that a dietary supplement is a
24 product or substance that is added to the diet.

25 Plaintiffs contend it's in addition to the

1 normal diet, a pill, capsule, tablet, powder, or liquid
2 form, which is not a conventional food, and effectively
3 increases the function of tissues when consumed.

4 Why do we think our construction is correct?

5 First, the parties agree that a dietary supplement at least
6 includes the idea that it is something added to a diet. On
7 that point, we don't seem to disagree. The specification
8 confirms that dietary supplements are products or substances
9 added to the diet. It doesn't expressly define the term.
10 But in the way that it's used it suggests they are things
11 added to the diet. And further dictionary support the
12 defendants' construction.

13 I understand the Court would at least entertain
14 that limited form of extrinsic evidence. If not, let me
15 know, and we will skip it when we come to the slide.

16 Why do we believe the plaintiffs' construction
17 is wrong? First of all, the specification does not limit
18 dietary supplement to those that are consumed, and yet their
19 construction suggests they must be consumed. Plaintiffs'
20 construction excludes or reads out a particular portion of
21 Example 2 in which a chicken broth was used as a means of
22 providing dietary supplementation. And the language of the
23 example itself shows that, and we will get to that in a few
24 moments.

25 Plaintiffs' construction also limits dietary

1 supplement to specific forms of dietary supplements, pill,
2 capsule, tablet, powder, or liquid, even though the
3 specification doesn't warrant limiting the term to a
4 particular form.

5 We also believe the specification does not limit
6 dietary supplements to those that increase the function of
7 tissues nor does it limit the invention to vegetarian diets,
8 to nonconventional foods. These are the summaries. We are
9 going to go through these individually. I wanted to preview
10 them before we jumped into the individual slides.

11 Quickly, here is the language from the beginning
12 of plaintiffs' construction that a dietary supplement is in
13 addition to the normal diet. We say it is a product or
14 substance that is added to the diet. We both seem to agree
15 that you add something to the diet as part of the
16 construction.

17 Slide 54, we show that the specification
18 confirms that dietary supplements are products or substances
19 added to the diet. In Column 1 it says natural food
20 supplements are typically designed to compensate for reduced
21 levels of nutrients in the modern human and animal diet.

22 Column 6, Lines 56 to 60 of the '361, shows an
23 example. During the supplementation period, an identical
24 feeding regime was implemented. However, each hand-fed meal
25 was supplemented with beta-alanine and L-histidine.

1 The term, in the sense that it's used, it's
2 something that is added to the diet.

3 The next slide is a dictionary definition. I
4 don't know --

5 THE COURT: Sure.

6 MR. HANSEN: Here we have two dictionary
7 definitions from the declaration of Mr. Walter, Exhibit D in
8 his first declaration. Dietary is used as an adjective.
9 Supplement is used as a noun. So we see the dietary
10 adjective form, of or relating to a diet, or the rules of a
11 diet. Then the noun form of supplement, the first
12 definition is something that completes or makes an addition.
13 And it actually uses dietary supplements in that particular
14 definition as an example of a type of supplement.

15 We believe that these dictionary definitions
16 further support defendants' construction that a dietary
17 supplement is simply proper substance added to the diet.

18 With that, let's look at why we believe
19 plaintiffs' construction is incorrect. On Slide 56 we
20 provide the first reason. The specification does not limit
21 dietary supplements to those that are consumed. We believe
22 that the word consumed to a fact-finder would ordinarily
23 connote some sort of taking it in orally. We believe that
24 that implication is not warranted because in several places
25 the specification makes clear that the compositions can be

1 provided by ingestion or infusion, e.g., injection. That is
2 from Column 3 of the '361 patent. And the composition can
3 be administered orally, enterally, through the digestive
4 tract or parenterally, outside the digestive tract.

5 Similarly, in Claims 9, 21, 34 of the '361
6 patent, they all describe the dietary supplement as being an
7 injectable formulation. We believe that this consumption
8 limitation suggests otherwise in plaintiffs' construction.

9 So we believe that it's improper to construe
10 this claim in a manner that's inconsistent with these
11 excerpts from the specification.

12 Just to be clear, this fourth claim here at the
13 bottom of Slide 56 is from the '084 patent, not one of the
14 three patents in suit. It is in the family that Mr.
15 DiGiovanni referred to in his presentation.

16 All right. Next reason we believe plaintiffs'
17 construction is incorrect is that it excludes or reads out
18 the chicken broth of Example 2. Now, I believe during
19 plaintiffs' presentation it was stated that the chicken
20 broth is not described as a dietary supplement, it's only
21 described as a natural food in the patent. We don't agree
22 with that, because of the language that is highlighted here
23 on Slide 57. Slide 57 says, it's discussing that Example 2
24 discusses the effect of supplementation of a normal diet.
25 And to show that effect, one of the experiments that was

1 done is to provide a chicken broth to patients, and then
2 have them ingest it, and then determine in their blood what
3 the concentration of free beta-alanine was.

4 So the way that the terms supplementation of a
5 normal diet are used in Example 2 in direct linkage with the
6 consumption of a chicken broth seems to us to compel the
7 conclusion that chicken broth is being used as an example of
8 a dietary supplement here.

9 If we look at Figure 8, which is a figure that
10 displays the data generated in Example 2, what we have done
11 here is highlight in blue what happened when the test
12 subjects ingested this chicken broth. And this is freed --
13 beta-alanine in the bloodstream. You can see from the blue
14 line that it went up quite a bit due to the ingestion of
15 chicken broth.

16 If plaintiffs were correct that a dietary
17 supplement cannot be a conventional food, then this chicken
18 broth example would not be within the scope of their
19 invention. And as the Court knows, it's rarely correct
20 under Federal Circuit precedent to construe a claim in a way
21 that reads out a preferred embodiment.

22 The next issue with plaintiffs' construction is
23 that it limits the term dietary supplement to specific forms
24 in which the dietary supplement is provided: pill, capsule,
25 tablet, powder or liquid. If you searched the '361 patent

1 for the word pill, you won't find it, nor will you find the
2 word capsule, nor will you find the word tablet, nor will
3 you find the word powder. You will find the word liquid and
4 you will find the word solid.

5 But the plaintiffs seek to define this term with
6 these specific forms that are not even disclosed in the
7 application.

8 For that reason we think it's improper as well
9 to limit dietary supplement to the forms specified in
10 plaintiffs' construction.

11 Next, plaintiffs' construction requires that in
12 order to be a dietary supplement, the material must
13 effectively increase the function of the tissues when
14 consumed. Now, the place that they seem to get this from is
15 Column 1 of the '361 patent starting at Line 18. It reads,
16 "Natural food supplements are typically designed to
17 compensate for reduced levels of nutrients in the modern
18 human and animal diet."

19 The next sentence reads, "In particular, useful
20 supplements increase the function of tissues when consumed."

21 That's the basis for the last limitation here,
22 "effectively increases the function of the tissues when
23 consumed."

24 We don't agree that that type of statement given
25 in the background of an invention defines what dietary

1 supplement means. Sure, it describes a class of useful
2 supplements as those that increase the function of tissues.
3 But other supplements may do other things. Maybe they add
4 something to the blood or provide things that are otherwise
5 missing.

6 But in our view that type of language is not the
7 type of language that is defining or limiting in the way
8 that plaintiffs would suggest in saying that it should be
9 used to construe dietary supplement.

10 So the next issue is, or the next thing that the
11 plaintiffs rely on to support their limitation to
12 conventional food is this excerpt from the '361 patent,
13 which reads that the compositions and methods can contribute
14 to correcting the loss of beta-alanine, L-histidine, or
15 creatine due to degradation or leaching of these
16 constituents during cooking or processing. The compositions
17 and methods can also contribute to correcting the absence of
18 these components from a vegetarian diet.

19 Okay. Fine. Those are possible benefits of
20 implementations of the invention. But that doesn't mean
21 that they limit the meaning of dietary supplement to a
22 conventional food. First of all, you can correct the loss
23 of beta-alanine or creatine due to degradation or leaching
24 by supplying more conventional food that has the desired
25 elements in it.

1 For example, if I eat a steak, and I don't get
2 enough of what I want in the way of beta-alanine, I can have
3 some chicken broth, according to Example 2 of the patent,
4 and that will be a way of addressing that issue.

5 So the mere fact that in certain foods there are
6 cooking losses doesn't mean that dietary supplements must
7 exclude conventional foods, as the plaintiffs suggest.

8 And finally, vegetarians obviously don't have in
9 their diet certain meat sources of beta-alanine like
10 carnosine. Well, that is fine. We don't dispute that the
11 invention is claimed broadly enough so that a vegetarian's
12 diet could be corrected. But that doesn't mean it needs to
13 be limited to that circumstance. Maybe just because a
14 particular vegetarian couldn't supplement their diet with
15 conventional foods because otherwise they wouldn't be a
16 vegetarian doesn't mean that the word dietary supplement has
17 to exclude conventional foods.

18 That is what we have on dietary supplement.

19 If the Court has any questions...

20 THE COURT: Thank you.

21 Your response, if any, Mr. Chambers.

22 MR. CHAMBERS: Your Honor, as pointed out by
23 defendants at JA3, Column 3, Lines 40 through 41, it says a
24 composition can be a dietary supplement. That clearly
25 indicates that a dietary supplement is something that is

1 different than -- a dietary supplement is something that is
2 different than just a composition. They pointed out that
3 there is a rule in the Patent Office that you shouldn't do
4 this. No less than three times do they seem to do this.

5 It is clearly something that is in dispute here
6 because we believe it's limiting. They believe it shouldn't
7 even be part of the claim.

8 In the second and third paragraphs of the
9 patent, they cover what dietary supplements are. We think
10 that when they are talking about chicken broth, they
11 describe chicken broth, as you recall, as a natural food.
12 That is on Line 68 of I guess JA68. And when you're looking
13 at Table 4, "broth" is there, but it's there as a control to
14 show the difference between that and beta-alanine. It is
15 something entirely different.

16 In terms of Column 1, Lines 18 through 25 of
17 Exhibit 3, under the patent law it's got to be useful to be
18 patentable. And so the fact that they say that this is
19 useful, that's just saying what's known under patent law.

20 Chicken broth, clearly, if you look through the
21 patent, it is not a preferred embodiment. It is something
22 that's mentioned and it's a control where they show the
23 difference between beta-alanine and chicken broth,
24 indicating that they think it's something different. And
25 you can find that in Table 4.

1 That's all we have on that one.

2 THE COURT: Thank you, counsel. Let's go on to
3 the next one.

4 MR. CHAMBERS: One other point.

5 Claim 9, 21 and 27, where they say it's
6 injectable, if it is a conventional food, clearly, it's not
7 something that is injectable, Your Honor. So it's something
8 that is different.

9 THE COURT: Okay. Which one is next for
10 plaintiff?

11 MR. CHAMBERS: Providing an amount of
12 beta-alanine to blood or blood plasma effective to increase
13 the beta-alanine dipeptide in the human tissue means
14 supplying to a human an amount of beta-alanine by ingestion.
15 We said it was by ingestion. We talked to the other side
16 and we proffered the idea that it was more than ingestion
17 because they had pointed out in their briefs that it could
18 also be by injection, which is infusion. So we proffered
19 this present term that you see that it means supplying to a
20 human an amount of beta-alanine or L-histidine by ingestion
21 or infusion and therefore causing an increase in
22 beta-alanine or L-histidine in blood or blood plasma above
23 the normal concentrations found in the typically fed state
24 and thereby increasing the synthesis of beta-alanine.

25 In the simplest form, Your Honor, we see that

1 basically means providing beta-alanine by ingestion or
2 infusion to increase beta-alanine in blood above its normal
3 concentration and increase beta-alanine with histidine.

4 We have indicated in our briefs why we believe
5 that it needs those attributes. And we will rest on the
6 briefs in that respect. But the reason we are concerned
7 about their particular term is that we don't understand what
8 is meant by indirectly or directly --

9 THE COURT: I have a question about that as
10 well.

11 MR. CHAMBERS: Okay.

12 THE COURT: They can respond.

13 Counsel, I am going to ask you not to go through
14 each of the slides.

15 MR. HANSEN: Should I jump into the individual
16 ones?

17 THE COURT: I think you should start off by
18 addressing the question I asked.

19 MR. HANSEN: Indirect or direct. That's fine.

20 THE COURT: That is troubling.

21 MR. HANSEN: To be clear, what we have done is
22 used the same language of the claim and have that in the
23 front. We used it because we understood that the plaintiffs
24 were going to try to limit the route of the providing.
25 Indirect or direct covers the universe. I don't think

1 it's -- that's a closed set. I don't think there is
2 anything not covered by direct or indirect. That language
3 just indicates, as does the limitation itself, that it can
4 be provided by any route. For example, in the patents --

5 THE COURT: Why not just say that? I don't know
6 how you would word it. My feeling is that perhaps directly
7 or indirectly will cause this fact-finder to scratch his
8 head and say, well, what do they mean? You have the benefit
9 and the luxury of speaking to the future fact-finder. You
10 don't have to worry about whether a jury understands. I am
11 telling you right now, I don't know what that means.

12 MR. HANSEN: We could certainly live with a
13 modification where it just makes clear that it doesn't
14 matter what the route of providing is, which is what we are
15 trying to do here.

16 THE COURT: Mr. Chambers, your view here?

17 MR. CHAMBERS: Our concern is they have really
18 expanded it by saying indirectly or directly. Now they are
19 saying it can be by any means.

20 This patent is about supplementation of the
21 diet, food supplements, and it's not about things like
22 exercise. It's known that exercise increases the dipeptide
23 in the muscle. Is that going to be something we are going
24 to be fighting over in the future? There has got to be a
25 limit.

1 THE COURT: Is exercise an issue?

2 MR. HANSEN: The claims we are talking about,
3 these are method claims. They don't have dietary supplement
4 in them. Even though the specification may speak to that --
5 for example, one of the asserted claims that recites this
6 limitation is Claim 1 of the '596 patent, and it's got two
7 limitations. One of them is the limitation that is on Slide
8 61, and the other one is that you expose the tissue to the
9 blood or blood plasma whereby the concentration of
10 beta-alanine and L-histidine is increased in the human
11 tissue. It's that broadly written.

12 Now, there is no limitation on the way that the
13 providing step occurs, and we just want to make that clear.
14 If to the Court that is clear enough on the record, then we
15 are not concerned about it. But the patent makes clear that
16 you can get -- what we are talking about here, Your Honor,
17 is what happens in the blood, not talking about what happens
18 at the point of delivery.

19 THE COURT: Understood.

20 MR. HANSEN: The patent explains that you could
21 ingest the single amino acid beta-alanine and it would go
22 through the digestive tract into the blood, but you could
23 also ingest carnosine, and it will break down into the
24 single amino acid, beta-alanine and L-histidine, and get to
25 the blood. If you inject it, it goes directly to the blood.

1 If you ingest it, it goes indirectly to the blood.

2 We were just trying to make that point, that
3 there is no limitation. Again, if the Court thinks that
4 it's clear on this record and that we don't need those
5 terms...

6 THE COURT: I am trying to see if there is a
7 basis for agreement here.

8 MR. CHAMBERS: Your Honor, a claim is construed
9 in view of the specification. When the specification is
10 going through and explaining how you supplement the diet,
11 and how you add beta-alanine to something, if somebody says,
12 well, it turns out that a little bit of exercise, like
13 walking down the street is going to do this, I don't think
14 that that is covered by the claims.

15 THE COURT: What is your reaction?

16 MR. HANSEN: I hadn't really considered or don't
17 know to what extent that would happen.

18 THE COURT: I think you are both talking about
19 some form of infusion or injection, something placing the
20 supplement inside the body.

21 MR. HANSEN: Something gets the material to the
22 blood.

23 THE COURT: To the blood.

24 MR. HANSEN: That is what the claim limitation
25 says.

1 THE COURT: And not by as indirectly as
2 exercise. That is why I keep asking, Mr. Chambers, and you
3 keep arguing. Just tell me there is no basis for agreement.

4 MR. CHAMBERS: There is no basis for agreement,
5 because as it turns out, Your Honor, it is definitely true
6 that the dipeptide increases in the muscle when there is
7 exercise.

8 This is a patent that is going to the
9 supplementation of the diet. It's not going to whether or
10 not you should get up and do a couple laps.

11 THE COURT: I think that's agreed upon. Right?
12 This is talking about supplementing the diet of a human
13 being. Right?

14 MR. HANSEN: I don't know how exercising would
15 be providing something. It's just supposed to be something
16 internal.

17 THE COURT: I guess maybe I am not making myself
18 clear. I don't understand why the parties can't agree. If
19 you agree on what the invention is, its purpose, its
20 intended purpose is to supplement the diet, and let's for
21 the moment say -- well, by means of ingesting some
22 supplement or injecting it in some way into the bloodstream,
23 and that's what seems to be at issue -- Mr. Chambers?

24 MR. CHAMBERS: Your Honor, that third
25 explanation that we had, where it was explained in its most

1 simple form, that covers exactly what you have said. It
2 covers ingesting it, eating it, or infusing, it covers all
3 those. And it doesn't have the problem of being direct or
4 indirect and pulling in things that we don't know where they
5 are going to go.

6 THE COURT: Why indirect or direct? I don't
7 understand the need.

8 MR. HANSEN: It was simply because there seems
9 to be a dispute as to whether there is any limitation on the
10 pathway by which the material can be provided.

11 There are several other issues that I want to
12 make sure we don't skip.

13 THE COURT: He just articulated some
14 limitations --

15 MR. HANSEN: They are --

16 THE COURT: Counsel, I am going to say the same
17 thing to you: Don't interrupt the Court.

18 MR. HANSEN: I am sorry.

19 THE COURT: Do you disagree with that?

20 MR. HANSEN: Yes.

21 THE COURT: Go ahead.

22 MR. HANSEN: Surely, the specification has
23 examples that are provided by certain routes. But in this
24 claim they chose not to incorporate any of those particular
25 routes and to just leave it written as broadly providing an

1 amount of this material to the blood or blood plasma.

2 And we have to ask ourselves, we have to step
3 back for a second and ask ourselves: What are the
4 circumstances under which we go into the specification and
5 use the embodiments to limit the scope of the claim? And
6 those circumstances are when they are described in a
7 mandatory way or as a requirement of the invention or
8 something along those lines.

9 We just simply didn't see anything in the
10 specification that describes what the plaintiff is
11 suggesting as mandatory in that fashion. Yes, it can be
12 provided by ingestion. Yes, it can be provided by
13 injection. Maybe there are other routes of delivery. But
14 they chose not to limit this claim term to a particular
15 route.

16 That is really the issue with indirect or
17 direct. But there are several other issues that I think we
18 want to make sure we get into with this particular
19 limitation.

20 THE COURT: I am not sure there are. But go
21 ahead.

22 MR. HANSEN: Sure, there are. If we look at
23 plaintiffs' construction, they are also requiring that you
24 cause an increase in blood or blood plasma of these
25 materials above normal concentrations in a typical fed

1 state.

2 Now, this limitation would require the
3 fact-finder to look at what is happening in the blood, make
4 some determination of what a normal fed state is, whatever a
5 typical fed state means, then look to see if it is above
6 that normal concentration.

7 That is nowhere in this limitation. It simply
8 says you provide some amount of material in the blood and
9 you increase the synthesis in the tissue.

10 THE COURT: Let me short-circuit this, because
11 it is the plaintiff who is in my mind right now swimming
12 upstream on this. I am going to let Mr. Chambers tell me
13 why this definition doesn't work: providing an amount, in
14 other words, adopting the defendants' definition absent the
15 words directly or indirectly.

16 You should sit down, Mr. Hansen, and let Mr.
17 Chambers take the podium.

18 MR. CHAMBERS: Your Honor, that is just the
19 claim language.

20 THE COURT: That's right. Exactly. What is the
21 matter with the claim language?

22 MR. CHAMBERS: There is some confusion as to
23 whether or not this would embrace such things as exercise,
24 which is not something that is described in the
25 specification. The specification goes to supplements. And

1 since the specification goes to supplementing and providing
2 something to a normal diet --

3 THE COURT: You know what I think that argument
4 is? It's lawyers over-lawyering, with due respect. We are
5 going to move on.

6 MR. CHAMBERS: Okay.

7 Your Honor, the next term is looking at
8 increasing the concentration of insulin in the blood. We
9 believe it means that the concentration of insulin is
10 increased by ingesting or perfusing, injecting insulin, or
11 agents that would stimulate the production of insulin. Once
12 again, we are in a situation where we don't want to have to
13 construe in the middle of a trial indirect and direct. We
14 are more concerned -- we rest on our briefs as to why that
15 particular construction is appropriate. But most
16 importantly, this is something that --

17 THE COURT: This is one where the defendants are
18 swimming upstream, Mr. Chambers. I want to hear from the
19 defendants on that.

20 MR. HANSEN: Your Honor, the issues here are the
21 same as on the last term. I don't see a need to argue
22 indirect or direct. You understand the reasons. If the
23 Court wants to leave the claim term as it is, which it would
24 be if we just dropped those two terms, we are okay with
25 that.

1 THE COURT: I will let you react, Mr. Chambers.

2 MR. CHAMBERS: Your Honor, of course, if you are
3 going to accept what we have right here --

4 THE COURT: Aren't we trying to increase the
5 concentration of insulin in the blood or blood plasma?
6 Aren't you both saying the same thing?

7 MR. CHAMBERS: Yes.

8 MR. HANSEN: No, because they take that basic
9 part of the limitation and then they add the method by which
10 it's --

11 THE COURT: By which it's done. Therein lies
12 your problem.

13 MR. HANSEN: Exactly.

14 MR. CHAMBERS: Your Honor, it is well known that
15 if you have a sugar pill that it's going to increase your
16 insulin level. If you eat some carbohydrate, it's going to
17 increase your insulin level.

18 The patent even talks about increasing the
19 insulin level that way.

20 So you can either ingest or infuse insulin or
21 some agent that stimulates the production of insulin.
22 Either way, you get the same result.

23 THE COURT: Go ahead, Mr. Hansen.

24 MR. HANSEN: We don't disagree that the
25 chemistry as described is correct. The issue is whether

1 that mechanism warrants limiting this claim term, which
2 speaks simply to an effect to a particular mechanism by
3 which the effect occurs.

4 THE COURT: That's the issue, Mr. Chambers, that
5 the defendants have with your -- and I am sure your slide
6 presentation and Mr. Hansen's presentation will tell me why
7 there is no support in the written description or the claims
8 for that. I suspect you are prepared to make that argument.
9 Right?

10 MR. HANSEN: Yes, we are.

11 MR. CHAMBERS: So I might as well sit down while
12 he does that.

13 THE COURT: No, no, because I am not prepared to
14 listen to it at this point. I understand what the argument
15 is. I have the benefit of the presentations. What I am
16 trying to do is get through this argument. But if I can get
17 you to tell me, we have now put a very fine point of where
18 the dispute is. Could you address your difference with the
19 defendants and tell me why you should prevail.

20 MR. CHAMBERS: The patents in suit indicate that
21 you can increase insulin by --

22 THE COURT: You need to talk to me, not him.

23 MR. CHAMBERS: -- by providing carbohydrates.
24 You don't have to give an injection of insulin or ingest
25 insulin in order to do it. An agent such as a carbohydrate,

1 something that is known to increase insulin, is just fine to
2 satisfy that claim term.

3 Exhibit 3, Column 3, Lines 42 through 45 --

4 THE COURT: If I accede to your suggestion, are
5 we running afoul of one of the canons of construction and
6 importing a limitation from the spec? That's a question. I
7 am not saying that I am making that conclusion. I am asking
8 you a question.

9 MR. CHAMBERS: Your Honor, I think we are
10 expanding it. In other words, what defendants would do is
11 they would narrow the way that you can get this insulin.
12 What we are doing is you can get it in an even broader way,
13 you can get it by giving insulin or you can get it by giving
14 some agent that will create insulin.

15 THE COURT: With respect, Mr. Chambers, it would
16 seem that the defendants' proposal is very broad. They are
17 saying directly or indirectly increase the concentration of
18 insulin -- that is a paraphrase -- in the blood plasma.
19 They don't place any limitations on it whatsoever.

20 MR. CHAMBERS: Your Honor, I can increase my
21 insulin by going out for a run. I can do things --

22 THE COURT: Wouldn't that be an indirect --

23 MR. CHAMBERS: That would certainly be an
24 indirect way of increasing it. But I don't think that is
25 what the patent is talking about. The patent only talks

1 about using these agents -- using things like carbohydrates.
2 They are not saying you go out and get yourself a two-mile
3 run and your insulin will spike and then you will have this
4 benefit. That is not what the patents are about. They are
5 about supplementing the diet with some kind of a dietary
6 supplement, not go out there and get some more exercise.

7 So agents that stimulate the production of
8 insulin, I think that that is actually keeping it broader
9 and yet keeping the construction of the term within the
10 realm of the patents in suit of the disclosure.

11 THE COURT: I will take a look.

12 MR. HANSEN: Do you want to hear from me again?

13 THE COURT: No. I have got the issue. Let's go
14 on to the next claim term.

15 MR. CHAMBERS: Your Honor, there is one other
16 term here, unit dosage. I think we will rest on the briefs
17 for that.

18 THE COURT: Are you comfortable with that, Mr.
19 Hansen, Mr. DiGiovanni?

20 MR. DiGIOVANNI: Yes. In fact, that was our
21 proposal.

22 THE COURT: All right, counsel. The Court will
23 reserve, take the matter under advisement. And I should
24 have my order out more or less within 30 days.

25 Are there any other matters that you need to

1 take up with me while you are here in town? Or are we okay?

2 MR. HANSEN: I think we are okay.

3 THE COURT: The parties are getting along well.

4 That is good.

5 Counsel, thank you for the presentation.

6 (Counsel respond "Thank you, Your Honor.")

7 (Court adjourned at 12:40 p.m.)

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10 Reporter: Kevin Maurer

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